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Code 4210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 424, 425, 427, 428, 495, and 512

[CMS-1832-F]

RIN 0938-AV50

Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for: the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; the Ambulatory Specialty Model; updates to the Medicare Diabetes Prevention Program expanded model; updates to drugs and biological products paid under Part B; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to the Medicare Promoting Interoperability Program.

DATES: These regulations are effective on January 1, 2026.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email. For all questions related to reporting a service on a claim, please contact your Medicare Administrative Contractor.

Michael Soracoe, Morgan Kitzmiller, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Hannah Ahn, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to potentially misvalued services under the PFS.

Julie Rauch, or *MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to Malpractice RVUs.*

Morgan Kitzmiller, Terry Simananda, or MedicarePhysicianFeeSchedule@cms.hhs.gov for issues related to Geographic Practice Cost Indices.

Mikayla Murphy, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Erick Carrera, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to office/outpatient evaluation and management visit inherent complexity add-on and Digital Mental Health Treatment services.

Maya Peterson, Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment for advanced primary care management services.

Sarah Leipnik, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to global surgery payment accuracy.

Pamela West, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to outpatient therapy services and KX modifier thresholds.

Michelle Cruse, Erick Carrera, Zehra Hussain, or Hannah Ahn *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to dental services inextricably linked to other covered medical services.

Zehra Hussain, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786-3377, Rebecca Ray, (667) 414-0879, and Jae Ryu, (667) 414-0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B. *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to complex drug administration.

Allison Cipro, (667) 414-0758, for issues related to Medicare Diabetes Prevention Program.

Sabrina Ahmed, (410) 786-7499, or SharedSavingsProgram@cms.hhs.gov, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and other quality reporting requirements.

Janae James, (410) 786-0801, or SharedSavingsProgram@cms.hhs.gov, for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology and shared losses mitigation.

Kari Vandegrift, (410) 786-4008, or SharedSavingsProgram@cms.hhs.gov, for issues related to Shared Savings Program participation options, and ACO participant and SNF affiliate change of ownership requirements.

Elisabeth Daniel, (667) 290-8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Benjamin Picillo or Genevieve Kehoe, AmbulatorySpecialtyModel@cms.hhs.gov, or 1-844-711-2664 (Option 4) for issues related to the Ambulatory Specialty Model.

Amy Gruber, (410) 786-1542, for issues related to Ambulance Extender provisions.

Kati Moore, (410) 786-5471, for inquiries related to the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program (QPP).

Trevey Davis, (410) 786-6600, for inquiries related to the Advanced Alternative Payment Models (APMs) track of QPP.

Jessica Warren, (410) 786-7519, and Lisa Marie Gomez, (410) 786-1175, for inquiries related to the Medicare Promoting Interoperability Program.

Lisa Parker, (410) 786–4949, or FQHC–PPS@cms.hhs.gov, for issues related to FQHC payments.

Michele Franklin, (410) 786–9226, or RHC@cms.hhs.gov, for issues related to RHC payments.

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a

chronological list of PFS **Federal Register** and other related documents. For the CY 2026 PFS final rule, refer to item CMS-1832-F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major annual rule revises payment policies under the Medicare PFS and makes other policy changes, including policies to implement certain provisions of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119-4, March 15, 2025), Further Continuing Appropriations and Other Extensions Act of 2024 (Pub. L. 118-22, November 16, 2023), Consolidated Appropriations Act, 2023 (Pub. L. 117-328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117-103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116-260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271, October 24, 2018), related to Medicare Part B payment. In addition, this final rule includes provisions regarding other Medicare payment provisions described in sections III. and IV. of this final rule.

This final rule updates policies for the Medicare Prescription Drug Inflation Rebate Program codified or finalized at parts 427 and 428 consistent with sections 1847A(i) and 1860D-14B of the Social Security Act (the Act). For the Medicare Part B Drug Inflation Rebate Program, this rule describes the identification of payment amount benchmark quarter in certain instances and the calculation for the Part B rebate amount in such instances. For the Medicare Part D Drug Inflation Rebate Program, this rule

finalizes a methodology for removal of units for a Part D rebatable drug for which a manufacturer provides a discount under the 340B Program for the applicable period beginning October 1, 2025, as well as the establishment of a voluntary 340B data repository for Part D claims for testing purposes.

This final rule modifies policies for the Shared Savings Program, which is a voluntary program that started in 2012. The program allows healthcare providers to form or participate in Accountable Care Organizations (ACOs), to be held accountable for the quality and total cost of care for an assigned population of Medicare fee-for-service (FFS) beneficiaries.

B. Summary of the Key Provisions

Section 1848 of the Act requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2026 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies, and other policies regarding programs administered by CMS.

Specifically, this final rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Enhanced Care Management (section II.G.)
- Outpatient Therapy Services and KX Modifier Thresholds (section II.H.)

- Advancing Policies to Improve Care for Chronic Illness and Behavioral Health Needs (section II.I.)
- Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services (section II.J.)
- Payment for Skin Substitutes (section II.K.)
- Strategies for Improving Global Surgery Payment Accuracy (section II.L.)
- Determination of Malpractice Relative Value Units (RVUs) (section II.M.)
- Geographic Practice Cost Indices (GPCIs) (section II.N.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Ambulatory Specialty Model (ASM) (section III.C.)
- Medicare Diabetes Prevention Program (MDPP) (section III.D.)
- Medicare Prescription Drug Inflation Rebate Program (section III.E.)
- Medicare Shared Savings Program (section III.F.)
- Changes to the Regulations Associated with the Ambulance Fee Schedule (section III.G.)
- Updates to the Quality Payment Program and Medicare Promoting Interoperability Program (section IV.)
- Collection of Information Requirements (section V.)
- Regulatory Impact Analysis (section VI.)

C. Summary of Costs and Benefits

Based on our estimates, the Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this final rule is economically significant under section 3(f)(1) of Executive Order 12866. As required by section 1848(d)(1)(A) of the Act, beginning in 2026, there will be two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant as defined in section 1833(z)(2) of the Act (referred to as the qualifying APM conversion factor) and another for other items and services (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year (or, for CY 2026, equal to the single conversion factor for CY 2025) multiplied by the update established under section

1848(d)(20) of the Act for such respective conversion factor for such year. Under these provisions, the 2026 qualifying APM conversion factor represents a projected increase of $0.39 (1.2 percent) from the current conversion factor of $32.3465. Similarly, the 2026 nonqualifying APM conversion factor represents a projected increase of $0.23 (0.7 percent) from the current conversion factor of $32.3465.

For a detailed discussion of the economic impacts, see section VI., Regulatory Impact Analysis, of this final rule.

II. Provisions of the Rule for the PFS

A. Background

In accordance with section 1848 of the Social Security Act (the Act), CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101-239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101-508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term "practitioner" is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the American Medical Association (AMA))/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we referred readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked to develop the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We have stated that we believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology or how the PE/HR data are used. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the

transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward is developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled "CY 2026 PFS final rule PE/HR" on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For CY 2026 final rule, we have incorporated the available utilization data for one new specialty, Epileptologists, which we recognized effective July 1, 2024 through our established process. We proposed to use proxy PE/HR values from Neurology for this new specialty, as there are no PPIS data for this specialty. We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

These updates are reflected in the "CY 2026 PFS final rule PE/HR" file available on the CMS website under the supporting data files for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial

indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Non-facility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and non-facility. The methodology for calculating PE RVUs is generally the same for both the facility and non-facility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE

RVUs are generally lower than the non-facility PE RVUs. We note, too, that in the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we proposed a modification in the allocation of indirect PE, described in detail in the CY 2026 PFS proposed rule.

(4) Services with Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different healthcare providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled "Calculation of PE RVUs under Methodology for Selected Codes" which is available on our website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/non-facility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that

fall into this category, instead of assigning a specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list annually. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, "always therapy" services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We did not make any proposals associated with the list of expected specialty assignments for low volume services, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for codes that meet these criteria for the CY 2026 PFS rule. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the significant adverse impact on MP RVUs that results from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of approximately 75 low volume HCPCS codes with recommended expected specialty assignments.

Response: For the past few years, we have reviewed the information provided by the commenters to determine whether the specialty assignments they recommended were appropriate for the services in question, based on determining if the recommended specialty matches the dominant specialty in the claims data. However, we have long held reservations on whether this is the most accurate method for implementing updates to the expected specialty assignments list. Since these updates to the list have never been formally proposed in the CY 2026 PFS proposed rule (90 FR 32593 through 32597), there has been no opportunity for interested parties to comment and provide feedback before the assignments are finalized in the final rule. We believe that it would provide greater transparency and more opportunities

for public comment if additions to the expected specialty assignments list were instead proposed in a future year's proposed rule.

Therefore, we are not finalizing any additions to the expected specialty assignments list in this final rule. We will instead review the list of approximately 75 low volume HCPCS codes submitted by commenters and propose additions to the list in next year's CY 2027 PFS proposed rule. We will also review any submissions for inclusion to the expected specialty assignments list by the same February 10th deadline that we have finalized in the past for consideration of RUC recommendations and invoice-based updates to supply and equipment pricing. We believe that synchronizing submissions to the expected specialty assignments list for low volume services with the same annual date used for RUC recommendations and invoice submissions will help standardize the process, while also providing more opportunities for feedback from interested parties by going through the annual comment process.

Comment: A commenter stated that there were four cardiothoracic surgery codes on the expected specialty assignments list which did not have the override applied. The commenter stated that these codes should meet the low volume criteria if their utilization were calculated using the number of services with no modifier or calculated using services with modifiers 22, 52 or 53. The commenter stated that if the utilization were calculated using data for all services, including modifiers 80, 82, 62 or AS, then the codes would not qualify for the 3-year average and requested clarification on the policy from CMS.

Response: We note again that we did not propose any changes to the methodology associated with the list of expected specialty assignments for low volume services. We continue to use an average of the most recent 3 years of claims data to determine low volume status (those that have fewer than 100 allowed services) based on using all of the information contained in the claims data, including all modifiers.

The full list of expected specialty assignments is included in the CY 2026 public use files, which are available on the CMS website under downloads for the CY 2026 PFS final rule at http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note*: For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled "Calculation of PE RVUs under Methodology for Selected Codes", the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

We note that for CY 2026, we proposed a change to the methodology so that when work RVUs are used to allocate indirect PE to the facility RVUs, they are assigned at one-half the amount allocated to the non-facility PE RVUs for that same service. This change is detailed later in this section.

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 as the denominator and Step 13 as the numerator, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See "Specialties excluded from ratesetting calculation" later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year 1 reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

We did not make any proposals associated with the allocation of indirect PE for some office-based services policy for CY 2026, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed concerns associated with the previously finalized adjustment to allocation of indirect PE for some office-based services policy, also known as the cognitive floor policy. The commenters stated that critical psychological and neuropsychological testing services are expected to receive a reduction in national average non-facility payment due to a technical calculation CMS uses to determine if a service meets specific criteria for the fee schedule's indirect PE floor (specifically a 0.40 non-facility PE to work RVU ratio). The commenters stated that these codes met the

requirement to receive this adjustment in 2025 but were projected to miss the technical screen by a slim margin in the 2026 proposed rule calculations, resulting in unexpected year-over-year payment fluctuations. The commenters stated that this current eligibility screen produces payment instability for services that are often on the cusp of eligibility, and in recent years developmental testing and neuropsychological testing services have been finalized as both eligible and ineligible depending on this calculation. The commenters requested that CMS use a rolling 3-year average of each services' non-facility PE and work RVUs when screening for the 0.40 non-facility PE to work RVU ratio, release eligibility calculations in each year's proposed rule for improved transparency into the technical screen, and adopt a 1-year notice period before finalizing a previously eligible code as newly ineligible for the indirect PE floor.

Response: We did not make any proposals associated with the allocation of indirect PE for some office-based services policy for CY 2026, the details of which were finalized in the CY 2018 PFS final rule (82 FR 52999 through 53000). As such, we are not finalizing any changes in this policy for CY 2026 PFS final rule, since the codes identified by the commenters do not meet the criteria for application of this policy as previously finalized. However, we will take the feedback from the commenters into consideration for potential use in future rulemaking.

(e) Setup File Information

- Specialties excluded from ratesetting calculation: To calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included to calculate the BN adjustment. They are displayed in Table A-B1.

TABLE A-B1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, for example, private ambulance companies, funeral

Specialty Code	Specialty Description
	homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (for example, drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- *Crosswalk certain low volume physician specialties*: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

- *Physical therapy utilization*: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

- *Identify professional and technical services not identified under the usual TC and 26 modifiers*: Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

- *Payment modifiers*: Payment modifiers are accounted for in creating the file consistent with the current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the

utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table A-B2 provides details in which the modifiers are applied.

TABLE A-B2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

We received many comments stating that CMS should not apply the multiple procedure payment reduction (MPPR) to always therapy services due to the way in which CMS finalized direct PE recommendations from the HCPAC in the CY 2025 PFS final rule (89 FR 97801 through 97803). However, we did not make any proposals associated with these always therapy services or the MPPR policy, and as such these comments are out of scope.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs*: The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/ (minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.

usage = variable, see discussion later in this final rule.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion later in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's "Estimated Useful Lives of Depreciable Hospital Assets" guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, (85 FR 84482 through 84483) we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance*: We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment

is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, in the proposed rule, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted in the CY 2026 PFS proposed rule (90 FR 32593) that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

- *Interest Rate*: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table A-B3.

TABLE A-B3: SBA MAXIMUM INTEREST RATES

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose any changes to the equipment interest rates for CY 2026.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to ensure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used

in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the 2017-based MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services (referred to as the “2017-based MEI”). We also finalized a delay of the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the rebased and revised 2017-based MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time had elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the implementation of the finalized 2017-based MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87

FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy.

We also solicited comments in the CY 2023 PFS proposed rule on when and how to best incorporate the 2017-based MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the 2017-based MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comments on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation, and many commenters expressed concerns with the redistributive impacts of the implementation of the 2017-based MEI in PFS ratesetting. Many commenters also noted the AMA's intent to collect practice cost data from physician practices, which could be used to derive cost share weights for the MEI and RVU shares.

In CY 2025 PFS rule (89 FR 97722), we stated that in light of the AMA's current data collection efforts and because the methodological and data source changes to the 2017-based MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, similar to our discussion of this topic in the CY 2024 PFS rule cycle (88 FR 78829 through 78831), we continued to believe that delaying the implementation of the finalized 2017-based MEI cost share weights for the RVUs was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. For these reasons, we did not propose to incorporate the 2017-based MEI in PFS ratesetting for CY 2024 and CY 2025. As we noted in the CY 2024 PFS final rule, many commenters on the CY 2024 PFS proposed rule supported our continued delayed implementation of the 2017-based MEI in PFS ratesetting (88 FR 78830). Most of these commenters recommended to us to pause consideration of other sources for the MEI until the AMA's efforts to collect practice cost data from physician practices concluded, although a few commenters recommended that we implement the MEI for PFS ratesetting as soon as possible. We stated that we agree with the commenters that it would be prudent, and avoid potential duplication of effort, to wait to consider other data sources for the MEI while the AMA's data collection activities were ongoing. We stated that as we discussed in the CY 2024 PFS final rule, we

continue to monitor the data available related to physician services' input expenses, but we were not proposing to update the data underlying the MEI cost weights at that time.

At the time of publication of the proposed rule, the AMA has concluded their data collection efforts and, in early 2025, submitted data from its Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys to CMS for us to consider implementing the PE/HR data and cost shares in PFS ratesetting for CY 2026. We appreciate the AMA's data collection efforts, and recognize the significant efforts required to develop the survey and collect the data. We have prioritized review of the submitted information during the first part of this year based on our longstanding interest in the value of updated practice expense information. At this time, however, we have substantive concerns about the accuracy and suitability of the PPI and CPI Survey data as an immediate replacement for the current PE/HR data and cost shares for use in CY 2026 PFS ratesetting. Due to overarching concerns with the data as described in the proposed rule and our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through routine updates to the MEI, we proposed not implementing the PE/HR or cost shares from the AMA's survey data at this time. Instead, we proposed maintaining the current PE/HR and 2006-based MEI cost shares for CY 2026 PFS ratesetting.

We discuss the topic of the MEI shares along with the implementation of PE/HR survey data from the AMA in section II.B.5 (Development of Strategies for Updates to Practice Expense Data Collection and Methodology) of this final rule; we are finalizing both of these topics as proposed.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2026 direct PE input public use files, which are available on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-fafor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to

increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve the relativity of values among codes. For example, as medical practice and technologies change over time, standards could be updated simultaneously for all codes with the applicable clinical labor tasks instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for "Availability of prior images confirmed", 2 minutes for "Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist", 2 minutes for "Review examination with interpreting MD", and 1 minute for "Exam documents scanned into PACS" and "Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue." In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, "Technologist QCs images in PACS, checking for all images, reformats, and dose page." These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we

determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on the number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the "Prepare room, equipment and supplies" (CA013) clinical labor activity were split into 2 minutes for the "Prepare room, equipment and supplies" activity and 1 minute for the "Confirm order, protocol exam" (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the "Prepare room, equipment and supplies" activity and remove the clinical labor time for the "Confirm order, protocol exam" activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we believe that the three total minutes of clinical staff time would be more accurately described by the CA013 "Prepare room, equipment and supplies" activity code, and we finalized these clinical labor refinements. We direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464) for additional details.

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. We direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584) for additional details.

Historically, the RUC has submitted a "PE worksheet" that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time, and among the medical specialties developing the recommendations. These variations have made it difficult for the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC mandated the use of a new PE worksheet for its recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations helps us simplify and standardize the hundreds of clinical labor tasks currently listed in our direct PE database. As in previous calendar years, to facilitate rulemaking for CY 2026, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule, we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY PFS 2019), 50/50 percent (CY PFS 2020), 75/25 percent (CY PFS 2021), and 100/0 percent (CY PFS 2022) split between new and old pricing. We believe that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy while maintaining stability and allowing interested parties to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2026, we proposed to update the price of 35 supplies and seven equipment items in response to the public submission of invoices following the publication of the CY 2025 PFS final rule (89 FR 97722). The 42 supply and equipment items with updated prices are listed in the valuation of specific codes section of the rule under Table A-B6, CY 2026 Invoices Received for Existing Direct PE Inputs.

We received a series of invoices associated with the SD339 supply prior to our February 10th submission deadline and are proposing to update its pricing accordingly for CY 2026 PFS proposed rule (90 FR 32593 through 32597), as detailed in Table A-B6, CY PFS 2026 Invoices Received for Existing Direct PE Inputs. We later received additional invoices associated with this supply several months following our February 10th deadline which arrived too late to be included in the updated pricing for this supply as shown in Table A-B6. Consistent with our previously finalized policy associated with the February 10th deadline (79 FR 67608), we noted in the proposed rule that we will review these invoices during the comment period following the publication of the CY 2026 PFS proposed rule (90 FR 32593) for potential inclusion in this final rule.

The following is a summary of the comments we received and our responses.

Comment: Several comments stated that they supported the proposed changes to supply and equipment pricing and recommended CMS to finalize these items as proposed. Supply and equipment items that commenters supported in their proposed pricing included the flow cytometer (EP014), Biodegradable Material Kit – PeriProstatic (SA126), Rezum delivery device kit (SA128), Esketamine (56 mg vial) (SH109), Esketamine (84 mg vial) (SH110), calibration beads (SL021), Isoton II diluent (SL084), lysing reagent (FACS) (SL089), Antibody Estrogen Receptor monoclonal (SL493), and 34 Beta E12 (SL496).

Response: We appreciate the support for our proposed pricing from the commenters.

Comment: A commenter submitted a yearly sampling of invoices to update the pricing of the "extended external ECG patch, medical magnetic tape recorder" (SD339) supply. The commenter submitted 26 additional invoices which were all priced at $345 and suggested CMS to update the SD339 pricing accordingly.

Response: We appreciate the submission of these additional invoices from the commenter. Also, since we previously received eight invoices associated with the SD339 supply at a price of $285, we will average these two sets of invoices together and finalize a CY 2026 price of $315 for this supply. We continue to welcome the submission of additional pricing data for assistance in valuing the SD339 supply.

Comment: A commenter stated that they previously submitted a request to CMS to update the pricing of the antigen, multi (pollen, mite, mold, cat) (SH007) supply. The commenter stated that based on their submitted invoices, they requested that the cost input for 1 mL of SH007 be increased to $17.07 instead of the $13.00 proposed by CMS. The commenter stated that while they appreciated the proposed increase in pricing, they had significant concerns that the pricing for the SH007 supply continued to be undervalued and was based on flawed assumptions regarding purchase volumes. The proposed pricing was based on averaging together the pricing of the 50 mL invoices while excluding the submitted 5 mL invoices; the commenter stated that allergists often purchase smaller quantities of allergens which may not require larger 50 mL purchases and allergy practices must observe a 1-year beyond-use date which could require them to discard a significant volume at the end of the year if their supplies were purchased in bulk.

Response: Although we appreciate the additional information supplied by the commenter, we

continue to believe that our proposed pricing of $13.00 is a more accurate valuation for the SH007 supply. The commenters noted that the SH007 supply is most commonly used in CPT code 95165 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens*), a high volume service that include 1 mL of the SH007 supply. CPT code 95165 is typically administered in multiple billings for the same patient on the same day; our claims data indicates that 10 billings of CPT code 95165 on the same day is the median result (with a mean of 12.54 billings). Given that each billing of CPT code 95165 includes 1 mL of the SH007 supply, and roughly 10-12 billings are typical for each patient encounter, it strains credulity to suggest that practitioners are typically purchasing the SH007 supply in its more expensive 5 mL quantities. While we agree that some practitioners will purchase the supply in 5 mL quantities, our PE methodology prices supplies based on the typical case, and the larger 50 mL quantity appears far more likely to be typical. We are therefore finalizing our proposed pricing of $13.00 for the SH007 supply based on an average of the submitted 50 mL invoices. We also note that the $13.00 price still represents a 45 percent increase in the price of the SH007 supply over its previous $8.96 pricing.

Comment: A commenter stated that CMS should use the updated WAC pricing for the Opfolda (65 mg capsule) (SH111) supply, which increased in 2025 to $33.52 per capsule. The commenter stated that they did not agree with the decision to use 3.5 capsules of the SH111 supply in HCPCS code G0138 (*Intravenous infusion of cipaglucosidase alfa-atga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga*) which presumed that the split between two patient weight groupings (40-50 kilograms and 50+ kilograms) is even. The commenter stated that the vast majority of patients (96 percent in clinical trial and 91 percent in assembled data) receive 4 capsules of OPFOLDA which aligns with the recommended dosage for patients weighing 50 kg or more. The commenter requested that CMS should update the SH111 supply quantity from 3.5 to 4 included in HCPCS code G0138 to match these findings.

Response: We agree with the commenter that the SH111 supply should be updated in pricing to match the most current WAC valuation; therefore, we are finalizing an increase in its price from $33.00 to $33.52. Regarding the quantity of the SH111 supply included in HCPCS code G0138, we did not solicit comments regarding this code or nominate it as potentially misvalued. As such, we stand by our previous

valuation of G0138, where this same topic of the SH111 supply quantity was discussed and finalized in last year's CY 2025 PFS final rule (89 FR 97816 through 97817).

Comment: Several commenters stated that the price and useful life of the platform mounted parallel bars (EQ201) equipment were out of date. The commenters stated that parallel bars are much different today than they were over 20 years ago and in order to best serve the patient, it is typical and standard for clinics to purchase parallel bars that have power adjustable heights and solid bases. The commenters stated that these features are much more expensive to purchase; however, they offer greater safety for patients who are at risk of falling. The commenters requested that CMS update the pricing for the EQ201 parallel bars to $18,956 and change the useful life to 5 years to reflect its mechanical components; they also submitted four invoices to support this pricing.

Response: We appreciate the additional information provided by the commenters, especially the submitted invoices for assistance in pricing. However, the motorized parallel bars described by the commenters and priced on the submitted invoices represent a fundamentally different type of equipment as compared with the platform mounted parallel bars described by EQ201. Our review of current market pricing for platform mounted parallel bars indicates that the current EQ201 pricing of $1599.96 remains accurate for this equipment, as it was readily available for order online at or below this pricing. Therefore, we are not finalizing an update to the price of the EQ201 equipment; however, we will add a new equipment item for "motorized parallel bars" (EQ414) priced at the requested $18,956 and with a useful life of 5 years. This new EQ414 equipment is not currently included in any CPT or HCPCS codes but is available for potential future inclusion in services if the motorized version of the parallel bars is determined to be the typical standard of care.

Comment: Several commenters recommended updating the price for the treadmill (EQ243) equipment to $8,120.64. The commenters stated that modern treadmills have multiple computerized and sensory components that allow for adjustable programs and tracking of vitals, and submitted five invoices to support this pricing update.

Response: Determining the typical market pricing for treadmill equipment is a difficult task due to the wide range of treadmills available for purchase; for example, the prices of the treadmills on the five invoices submitted by the commenters ranged from a low of $7,125.10 to a high of $26,064.00. Based on

our review of the current pricing of medical treadmills, it appears that the current EQ243 price of $4,860.79 remains highly typical, including matching the pricing of several other medical treadmill models available from the same manufacturer listed on the submitted invoices. The specific model listed on these invoices is the "performance plus" version of a medical treadmill which appears to be situated at the high end of the market; it does not appear to reflect typical pricing and therefore we are not finalizing an increase to the price of the EQ243 treadmill equipment.

Comment: Several commenters requested that CMS update and modify the price of the exercise equipment (EQ118). The commenters stated that the EQ118 equipment currently reflects exercise equipment and includes a treadmill, bike, stepper, and upper body ergometer (UBE). The commenters recommended removing the treadmill from this package and having it as a stand-alone piece of equipment, while steppers and UBE's are not typical pieces of exercise equipment in a physical therapy clinic any longer. The commenters requested that CMS modify the equipment included in item EQ118 to reflect a total gym, recumbent bike, and cable columns. Commenters stated that pricing for this equipment item should be increased to $16,700 and submitted a series of invoices to support their requested pricing.

Response: The exercise equipment described by the commenters and priced on the submitted invoices represent a fundamentally different type of equipment as compared with the existing EQ118 item. The current EQ118 equipment is based on pricing a treadmill, bike, stepper, UBE, pulleys, and balance board; in contrast, the equipment collection described by the commenters constitutes a total gym, recumbent bike, and cable columns. Therefore, we are not finalizing an update to the price of the EQ118 equipment; however, we will add a new equipment item for "exercise equipment (total gym, recumbent bike, and cable columns)" (EQ415) priced at the requested $16,700. This new EQ415 equipment is not currently included in any CPT or HCPCS codes but is available for potential future inclusion in services if this alternate version of exercise equipment is determined to be the typical standard of care.

Comment: Several commenters stated that the practice of manual therapy (CPT code 97140) and massage therapy (CPT code 97124) typically includes the use of manual therapy hand instruments. The commenters stated that these instruments are not included in the equipment for these codes and requested that CMS add a new equipment item for manual therapy instruments at a price of $1,795 and a useful life

of 15 years for CPT codes 97140 and 97124. Commenters submitted one invoice to support this requested pricing.

Response: We concur with the commenters that the submitted invoice at a price of $1,795 appears to be the current market price for manual therapy hand instruments. We will therefore add a new equipment item for "manual therapy hand instruments" (EQ416) priced at the requested $1,795 and with a useful life of 15 years. However, since we do not have any data at the moment to support the claim from the commenters that the use of these manual therapy hand instruments is typical in CPT codes 97140 and 97124, we are not adding them to the equipment inputs for these two codes. The new EQ416 equipment is not currently included in any CPT or HCPCS codes but is available for potential future inclusion in services if the use of manual therapy hand instruments is determined to be the typical standard of care.

After reviewing the comments, we are finalizing our supply and equipment pricing updates as proposed, with the modifications listed above in response to the comments.

We proposed not to update the price of another eight supplies and one equipment item, which were the subject of public submission of invoices. Our reasons that we proposed not to update to these prices are detailed in the proposed rule, and we solicited additional information from interested parties for assistance in pricing these supplies:

- *Radiation treatment vault (ER056)*: We received pricing information associated with the radiation treatment vault from an interested party. However, this pricing information contained numerous costs associated with building construction which would not be included on a traditional invoice, such as surveying, plumbing and HVAC expenses, drywall packaging, and the installation of electrical equipment. As we previously stated in the CY 2021 PFS final rule (85 FR 84482 through 84483) about similar costs associated with proton beam treatment delivery services, the expenses associated with constructing new office facilities fall outside of our direct PE methodology and would be more accurately classified as a form of building maintenance or office rent under indirect PE (85 FR 84626). We do not agree that construction costs should be included as a form of direct PE because they are not individually allocable to a particular patient for a particular service. Therefore, we do not believe that it would serve the interests of relativity to include these building construction costs for the radiation treatment vault as a type of direct PE expense. In the absence of other pricing information associated with the radiation

treatment vault, or pricing of the vault absent these building construction costs, we proposed to maintain its current price of $773,104.

- *Congo red kits (SA110) and UltraView Universal DAB Detection Kit (SL488):* We received three invoices from interested parties requesting an increase in the price of the SA110 supply from $6.80 to $20.12 and another three invoices from interested parties requesting an increase in the price of the SL488 equipment from $12.28 to $41.26. In both cases, we do not understand how the typical price of these supplies could be increasing by such a large amount, tripling the current price in both cases, given that the price of both supplies was recently updated. Both the SA110 supply and the SL488 supply had their prices updated in the CY 2024 PFS final rule, with the SA110 supply increasing from $6.16 to $6.80 and the SL488 supply increasing from $9.70 to $12.28 (88 FR 78966 through 78967). We do not believe that the typical price for these supplies would increase to such a great degree given that their pricing was already recently updated for CY 2024; therefore, we proposed not to update.

- *Catheter, balloon, rectal pressure (SD017); catheter, pressure, urodynamic (SD027); and transducer dome (pressure) (SD125)*: We received one invoice from interested parties for each of these three supplies. Interested parties requested an increase in the price of the SD017 supply from $35.89 to $74.00, an increase in the price of the SD027 supply from $19.35 to $86.80, and an increase in the price of the SD125 supply from $3.58 to 17.32. However, in each of these three cases, it was unclear if the item on the invoice matched the supply item in question. The invoice for the SD017 supply listed a "Abdominal Sensor Catheter", the invoice for the SD027 supply listed a "Single Sensor Catheter", and the invoice for the SD125 supply listed a "transducer cartridge with luer lock". Given the differences between the names of the items in question, and the significant increases in requested pricing, we proposed not to update the pricing of these three supplies as we cannot verify that the invoices refer to the same supply items.

- *Electrode, surface (SD062)*: We received one invoice from interested parties requesting a decrease in the price of the SD062 supply from $1.58 to $0.34. The invoice appeared to state that there are 10 copies of 10 packs of 3 electrodes which, when dividing the total price of $103 by 300 electrodes, results in a price of $0.34 per electrode. We do not believe that the interested parties intended to submit an invoice resulting in a 78 percent decrease in pricing for the SD062 supply, and we are not convinced

that we have correctly understood the unit quantity for this item. As a result, we proposed not to change the pricing of the SD062 supply at this time.

- *Biohazard specimen transport bag (SM008)*: We received one invoice from interested parties requesting an increase in the price of the SM008 supply from $0.087 to $0.750, an increase of more than 750 percent. However, when we reviewed the invoice, we determined that it referred to a different type of disposal bag than the biohazard specimen transport bag described by the SM008 supply, which explained the disparity in the pricing. We therefore proposed not to update the pricing of the SM008 supply.
- *Wipes, lens cleaning (per wipe) (Kimwipe) (SM027):* We received one invoice from interested parties requesting an increase in the price of the SM027 supply from $0.04 to $0.33, an increase of approximately 700 percent. However, when we reviewed the supply in question, we found that lens cleaning wipes were readily available for purchase at the current price of $0.04 per wipe. We therefore proposed not to update the pricing of the SM027 supply.

The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the CMS decision not to reduce the pricing on the surface electrode (SD062) supply from $1.58 to $0.34. The commenter stated that it was their experience that a single pack of electrodes includes 3-4 electrodes per pack; these electrodes are sometimes sold in bulk orders of ten packs or twenty packs, but not ten sets of ten packs of three electrodes as the interested party indicated.

Response: We appreciate the support for our proposed pricing from the commenter.

Comment: A commenter disagreed with the proposal to maintain the current price of $773,104 for the radiation treatment vault (ER056) equipment. The commenter stated that the radiation treatment vault is unlike anything else in medicine as it is designed and constructed to safely house a specific high-energy radiation treatment machine within its space. The commenter stated that the vault must comply with specific Federal and State licensing regulations to protect patients, clinic staff, and the public from radiation exposure, and the Internal Revenue Service rules treat radiation treatment vaults as medical equipment. The commenter supported maintaining the classification of the vault as a direct PE input and

encouraged CMS to consider alternative methods for identifying and valuing the vault separate from general construction expenses.

Response: We appreciate the additional information supplied by the commenter regarding the radiation treatment vault; we have also noted many of the challenges associated with pricing this unusual equipment and remain interested in different sources of data to assist in its valuation.

After reviewing the comments, we are finalizing our proposal not to update the pricing of these supply and equipment items.

(1) Invoice Submission

We remind readers that we routinely accept public submissions of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often, these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the CY 2026 PFS proposed rule (90 FR 32593 and will consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

(2) Supply Pack Pricing Update

Interested parties previously notified CMS that they identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The interested parties indicated that CMS should rectify these mathematical errors as soon as possible to ensure that the sum correctly matches the totals from the individual items, and they recommended that we resolve these pricing discrepancies in the supply packs during CY 2024 rule. The AMA RUC convened a workgroup on this subject and submitted recommendations to update pricing for a series of supply packs along with the RUC's comment letter for the CY 2024 rule cycle.

We appreciated the additional information and RUC workgroup recommendations regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost

revisions in the pricing of supply packs and because we did not propose to address supply pack pricing in the CY 2024 proposed rule, we stated in the CY 2024 final rule that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes, which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We stated that interested parties would be better served if we comprehensively addressed this topic during future rulemaking in which commenters could provide feedback in response to proposed pricing updates (88 FR 78833 through 78834).

For CY 2025, we proposed implementing the supply pack pricing update and associated revisions as recommended by the RUC's workgroup (89 FR 97726 through 97727). We proposed to update the pricing of the "pack, cleaning and disinfecting, endoscope" (SA042) supply from $19.43 to $31.29, to update the pricing of the "pack, drapes, cystoscopy" (SA045) supply from $17.33 to $14.99, to update the pricing of the "pack, ocular photodynamic therapy" (SA049) supply from $16.35 to $26.35, to update the pricing of the "pack, urology cystoscopy visit" (SA058) supply from $113.70 to $37.63, and to update the pricing of the "pack, ophthalmology visit (w-dilation)" (SA082) supply from $3.91 to $2.33. As recommended by the RUC workgroup, we also proposed to delete the "pack, drapes, laparotomy (chest-abdomen)" (SA046) supply entirely. The updated prices for these supply packs were listed in the valuation of specific codes section of this rule under Table A-B6, CY 2025 Invoices Received for Existing Direct PE Inputs (89 FR 97852).

In accordance with the RUC workgroup's recommendations, we also proposed to create eight new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes, as they are, again, components contained within previously existing supply packs. We proposed to add:

- The kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- The Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;

- The drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- The drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- The post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- The y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- The ortho-phthalaldehyde 0.55percent (for example, Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- The ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The new supply pack component items were listed in the valuation of specific codes section of in the rule under Table A-B8, CY 2025 PFS (89 FR 97722) New Invoices (89 FR 97853).

We also proposed the following additional supply substitutions based on the recommendations of the RUC workgroup. We proposed to remove the deleted SA046 supply pack and replace it with the drape, sterile, fenestrated 16in x 29in (SB011) supply for CPT codes 19020, 19101, 19110, 19112, 20101, and 20102. We proposed to remove the deleted SA046 supply pack and replace it with two supplies – the drape, sterile, three-quarter sheet (SB014) and the drape, towel, sterile 18in x 26in (SB019) – for CPT codes 19000 and 60300. We proposed to remove the deleted SA046 supply pack and replace it with 2 supplies – the drape, towel, sterile 18in x 26in (SB019) and the newly created Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply – for CPT codes 22510, 22511, 22513, and 22514. We proposed to remove the deleted SA046 supply pack without replacing it with anything for CPT code 22526; the RUC workgroup did not make a recommendation on what to do with CPT code 27278, which also previously contained the SA046 supply pack. Therefore, we also proposed not to replace the SA046 supply pack with any supplies for this code. The RUC workgroup also recommended removing the SA046 supply pack from CPT code 64595 with no replacement; however,

this code was recently reviewed at the April 2022 RUC meeting and it no longer includes the SA046 supply.

In the comments on the CY 2025 PFS proposed rule (89 FR 97727), several commenters supported the proposed supply pack pricing update as recommended by the RUC workgroup, however they indicated concern over the proposed decrease in the price of the urology cystoscopy visit pack (SA058) from $113.70 to $37.63. The commenters stated that the proposed pricing reduction in the SA058 supply could result in drastic payment rate cuts for physicians performing cystoscopy services in the office setting. The commenters requested that CMS either delay the pricing update or phase-in the supply pack changes over a 4-year period like it has done for other PE changes with significant redistributive effects, allowing independent urology practices to better prepare for the negative financial impact this change will have.

After considering these comments, we agreed that the use of a phased-in transition period would be appropriate to allow practitioners to adjust to the updated pricing of these supplies. During our previous supply and equipment pricing update in the CY 2019 PFS final rule (83 FR 59475), we finalized a policy to phase in any updated pricing that we established during the 4-year transition period for very commonly used supplies and equipment, such as sterile gloves (SB024) or exam tables (EF023), even if invoices were provided as part of the formal review of a code family. Based on this previously established policy, we finalized the use of a pricing transition for three supply packs in Table A-B4.

TABLE A-B4: CY 2025 SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33

Following the same pattern as our previous supply/equipment and clinical labor pricing updates, we finalized the implementation of this pricing transition over 4 years such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2025 PFS (89 FR 97722), one-third of the difference between the CY 2025 PFS (89 FR 97722) price and the final price is implemented for CY 2026 PFS, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028. For the other proposed supply packs, the cystoscopy drapes pack (SA045) is only included in 7 HCPCS codes

and the ocular photodynamic therapy pack (SA049) is only included in a single HCPCS code which do not meet these criteria established in previous rulemaking and described previously in this section. Therefore, we finalized each of them at their updated pricing for CY 2025 PFS (89 FR 97722) as proposed in the proposed rule. We believe that the use of this pricing transition will minimize any potential disruptive effects during the 4-year transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply packs.

Several commenters also stated that although five incomplete packs would have their pricing updated in the proposed rule, mathematical errors still remained for a number of additional supply packs. Commenters stated that only 3 of the 18 affirmed packs were priced correctly to match their components and provided tables showing the pricing of an additional 15 packs that needed mathematical correction by deconstructing the packs to determine the correct price through summing their individual components. Commenters requested that CMS initiate a correction of the packs pricing such that the sum of the individual components match the price of the corresponding pack as detailed in Table A-B5:

TABLE A-B5: SUPPLY PACK PRICING REQUESTED BY CY 2025 COMMENTERS

HCPCS Codes	Item Name	CMS Code	Current Price	New Price	% Change
111 codes	pack, basic injection	SA041	$10.45	$17.28	65%
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$1.98	-61%
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$1.35	-50%
239 codes	pack, pelvic exam	SA051	$20.16	$2.81	-86%
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$9.90	106%
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$11.54	111%
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$10.34	124%
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$18.18	149%
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$16.05	159%
120 codes	pack, drapes, ortho, large	SA080	$37.30	$25.38	-32%
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%
119 codes	pack, protective, ortho, large	SA083	$10.86	$14.75	36%
27 codes	pack, protective, ortho, small	SA084	$5.99	$8.15	36%

While we shared the concerns of the commenters regarding the need for accuracy in the pricing of these supply packs, we had reservations about their potential for pricing disruptions. Ten of these supply packs are included in the direct PE inputs for at least 100 HCPCS codes, and three of the packs are included in more than 1000 HCPCS codes. Many of these pricing updates would lead to drastic changes in pricing for these supply packs which are included in hundreds of HCPCS codes, such as the SA051 pelvic exam pack decreasing in price from $20.16 to $2.81 (-86 percent) and the SA048 minimum multi-

specialty visit pack decreasing in price from $5.02 to $1.98 (-61 percent). We were particularly concerned that these changes in supply pack pricing could lead to significant shifts in the overall PE RVU for affected HCPCS codes, without these proposed rates appearing in the proposed rule or allowing any opportunity for public comment.

Therefore, we did not finalize pricing updates for these additional 15 supply packs as requested by commenters. We anticipated returning to this subject in future rulemaking to allow any changes in associated pricing for HCPCS codes to appear in the proposed rule and provide an opportunity for the public to comment. Should these supply pack pricing updates be proposed in future rulemaking, we anticipated that we might propose the same pricing transition described above due to the number of potentially affected HCPCS codes. We finalized all of the other supply pack pricing changes as proposed, with the exception of the 4-year pricing transition for three supply packs as described previously in this section.

For CY 2026, we proposed to continue implementing the supply pack pricing update and associated revisions as previously recommended by the RUC's workgroup. We proposed to update the price of the 15 supply packs detailed in Table A-B5 which were received too late in CY 2025 PFS (89 FR 97722) to allow for proposed pricing or public comment. In the case of the surgical instruments cleaning pack (SA043), the moderate sedation pack (SA044) and the small ortho drapes pack (SA081), the proposed pricing update is modest enough that we proposed these supplies move immediately to their final prices for CY 2026.

For the 12 other supply packs, we proposed that they be incorporated into the muti-year supply pack pricing transition finalized in CY 2025 rulemaking. Rather than having two separate 4-year pricing transitions associated with supply packs, we proposed that these 12 additional supply packs fold into the previous pricing transition using the same methodology, such that one-third of the difference between the CY 2025 PFS (89 FR 97722) price and the final price is implemented for CY 2026, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028 (89 FR 97728). With the inclusion of the SA042, SA058, and SA082 supply packs which began their pricing transition last year for CY 2025, we proposed the total supply pack pricing update detailed in Table A-B6:

TABLE A-B6: CY 2026 SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33
SA041	111	$10.45	$17.28	-	$12.73	$15.00	$17.28
SA048	4568	$5.02	$1.98	-	$4.01	$2.99	$1.98
SA050	168	$2.72	$1.35	-	$2.26	$1.81	$1.35
SA051	239	$20.16	$2.81	-	$14.38	$8.59	$2.81
SA052	1079	$4.80	$9.90	-	$6.50	$8.20	$9.90
SA053	469	$5.47	$11.54	-	$7.49	$9.52	$11.54
SA054	1708	$4.62	$10.34	-	$6.53	$8.43	$10.34
SA055	12	$7.30	$18.18	-	$10.93	$14.55	$18.18
SA056	24	$6.20	$16.05	-	$9.48	$12.77	$16.05
SA080	120	$37.30	$25.38	-	$33.33	$29.35	$25.38
SA083	119	$10.86	$14.75	-	$12.16	$13.45	$14.75
SA084	27	$5.99	$8.15	-	$6.71	$7.43	$8.15
SD089	100	$20.56	$41.15	-	$27.42	$34.29	$41.15

This table also includes the hydrophilic guidewire (SD089) supply which we are proposing to transition in pricing over 3 years given its inclusion in approximately 100 HCPCS codes. We continue to believe that the use of this pricing transition will minimize any potential disruptive effects during the transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply items.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported the proposals associated with supply pack pricing. Commenters stated that they appreciated the proposal to initiate correction of the remaining packs pricing such that the sum of the individual components will match the price of the corresponding pack by CY 2028. Commenters stated that they supported the proposal to move the prices of the surgical instruments cleaning pack (SA043), the moderate sedation pack (SA044), and the small ortho drapes pack (SA081) to their final prices for CY 2026 due to their modest pricing changes. Commenters also stated that they agreed with the inclusion of the SD089 hydrophilic guidewire supply in the updated pricing transition.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters stated that although they appreciated the 4-year pricing transition for the SA051 pelvic exam pack, they remained concerned that even a phased-in reduction will materially

decrease practice expense RVUs for a broad range of services furnished by gynecologists. Commenters stated that the proposed reduction did not reflect the realities of practice expenses in today's environment since supply and labor costs continue to rise due to inflation and market pressures. Commenters stated that they were considering submission of updated invoices and cost data related to the pelvic exam supply pack and would welcome the opportunity to engage with CMS further to ensure pricing accurately reflects costs across a range of practice settings.

Response: We share the concerns of the commenters regarding the large decreases in pricing associated with the SA051 and SA058 supply packs, which is why we finalized the use of a phased-in transition period in the CY 2025 PFS final rule (89 FR 97722). However, we also believe in the importance of valuing supply items at the most accurate market-based pricing available, and therefore we cannot continue to price these supply packs at rates much higher than the cost of the individual components that make up the total packs. We welcome the submission of updated invoices and other cost data associated with these supply packs for potential inclusion in future rulemaking.

Comment: A commenter stated that the proposal to reduce the value of the SA048 minimum multi-specialty visit pack by $1.01 was not the result of a formal, transparent process. The commenter stated that the proposal represented a significant reduction in the PE value of occupational therapy evaluation codes as well as the valuation of 4,565 other codes. The commenter stated that CMS should not finalize any reduction to the SA048 supply pack pricing at this time given the lack of transparency and the significant impact on reimbursement. Another related commenter stated that CMS should not finalize any supply pack pricing updates until invoices have been provided to support such a change.

Response: We noted in last year's CY 2025 PFS final rule (89 FR 97722), that we were particularly concerned that these changes in supply pack pricing could lead to significant shifts in the overall PE RVU for affected HCPCS codes, without these proposed rates appearing in the proposed rule or allowing any opportunity for public comment. Therefore, we delayed any proposals associated with the SA048 supply pack until the CY 2026 PFS proposed rule (90 FR 32593, in the interests of transparency and to create an opportunity for interested parties to provide feedback. We agree with the commenter that a large number of CPT and HCPCS codes will be affected by the proposed pricing changes to the SA048 supply pack. However, as noted previously in this section, we also believe in the importance of valuing

supply items at the most accurate market-based pricing available, and therefore we cannot continue to price these supply packs at rates much higher than the cost of the individual components that make up the total packs. We also remind interested parties that we are transitioning these pricing changes over the next three years to help minimize any potential disruptive effects on valuation.

After consideration of the public comments, we are finalizing our supply pack pricing policies as proposed.

c. Technical Corrections to Direct PE Input Database and Supporting Files

Following the publication of the CY 2025 PFS final rule (89 FR 97722), we received a request from the RUC to remove all equipment items priced below $500 from the CMS ratesetting database. The RUC stated that since CMS has defined that medical equipment must be at least $500 and all equipment inputs under $500 are considered indirect expense, the 11 current equipment items under this threshold should no longer be listed as equipment. The RUC requested that CMS remove these items from its equipment list and from the specific HCPCS codes to conform to the definition of direct medical equipment and to ensure that the rule remains consistently applied.

We appreciate the RUC bringing this topic to our attention. However, we proposed not to remove these 11 equipment items that fall under the $500 threshold from the CMS ratesetting database. These equipment items have historically been included as direct PE inputs in their respective HCPCS codes for the last 2 decades and, given the very small valuation associated with their use (such as the ED004 digital camera priced at approximately 0.06 cents per minute of use), we do not believe that it is necessary to remove them from the database. We believe that it better serves relativity by continuing to maintain these equipment items due to their historical inclusion in their associated HCPCS codes, as opposed to the removal of long-standing direct PE inputs which may cause unnecessary confusion and lead to concern that the valuation of these services would be negatively impacted. We solicited comments on whether to maintain or remove these equipment items.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters continued to disagree with the CMS proposal to retain these 11 historic equipment items in the ratesetting database. The commenters stated that this was faulty reasoning

and relativity should be based on actual resource costs using standard definitions, not historical inclusion. The commenters recommended that CMS remove all equipment items under $500 from its equipment list and from the specific codes to conform to the definition of direct medical equipment.

Response: We proposed to maintain these 11 equipment items out of a desire to maintain historical continuity with prior ratesetting and to minimize any disruption on valuation of their associated services. However, since we received no comments requesting that these historic equipment items be maintained, we concur with commenters that these equipment items should be removed from the ratesetting database and any associated CPT and HCPCS codes. The affected equipment items are as follows:

TABLE A-B7: REMOVAL OF EQUIPMENT ITEMS PRICED BELOW $500

Equipment Description	CMS Code	Useful Life	Purchase Price
endoscope, ultrasound radial probe	ES045	7	0.00
Injector, Provis (for angiography room)	EL049		0.00
ultrasound digital scope, endoscopic ultrasound	ES091		0.00
Respiratory Impedance Plethysmography Belts (pair)	EQ337	5	87.00
camera, digital (6 mexapixel)	ED004	5	152.50
Respiratory impedance Plethysmography Belts (pair) (Pediatric)	EQ349	5	199.75
Diabetes Educator Curriculum	EQ306	5	200.00
work samples, small tools (Valpar 1)	EQ267	7	361.20
pulse oximetry recording software (prolonged monitoring)	EQ212	5	387.00
kit, vision	ES058	10	410.00
slide warmer	EP051	7	425.59

We are finalizing the removal of these 11 equipment items priced below $500 from the ratesetting database and their associated CPT and HCPS codes.

We also received a request from the RUC to update the names of several supplies and equipment items in the CMS ratesetting database. The RUC stated that these naming changes would remove specific products or brand names and more accurately describe the items in question. We agree with the RUC and we proposed naming changes for the following supplies and equipment items:

- EQ392: We proposed to rename the “heart failure patient physiologic monitoring equipment package” to “patient physiologic monitoring equipment package”.
- ER089: We proposed to rename the “IMRT Accelerator” to “Radiation Treatment Delivery Linear Accelerator”.

- SD253: We proposed to rename the "atherectomy device (Spectronetics laser or Fox Hollow)" supply to "atherectomy device".
- SD254: We proposed to rename the "covered stent (VIABAHN, Gore)" to "covered stent (VIABAHN)".

We received a separate request from the RUC for a technical correction involving CPT code 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*). The RUC stated that there was a potential issue with the intraservice work time for CPT code 65780, which was recommended by the RUC with 35 minutes of work time and finalized by CMS with no work time refinements. However, CPT code 65780 was listed with 25 minutes of intraservice work time in the work time public use file issued with the CY 2025 PFS final rule (89 FR 97722); the RUC questioned whether this was a potential technical error. We have reviewed CPT code 65780 and concluded that the intraservice work time was unintentionally listed with the incorrect work time of 25 minutes; we proposed to correct this to the intended work time of 35 minutes. We note that the total work time of 192 minutes was listed correctly for CPT code 65780 and does not require a technical correction.

We also received a request from the RUC for a technical correction involving CPT code 15851 (*Removal of sutures or staples requiring anesthesia (that is, general anesthesia, moderate sedation)*). The RUC stated that CPT code 15851 continued to receive PE RVUs in the non-facility setting despite no longer having any direct PE inputs following its review at the January 2022 RUC meeting. Since CMS finalized the RUC's recommended lack of direct PE inputs for CPT code 15851 in the CY 2023 PFS final rule, the RUC questioned whether this was a potential technical error. We have reviewed CPT code 15851 and concluded that the continued assignment of PE RVUs in the non-facility setting is an unintended technical error; we proposed to correct this code by removing the non-facility PE RVUs for CY 2026.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter stated their support for all three technical corrections. The commenter agreed that the name changes more accurately describe the inputs and appreciated their implementation, as well as appreciated the technical corrections to CPT codes 65780 and 15851. A separate commenter agreed with the shift toward a generic name for the EQ392 equipment and supported the CMS renaming

proposal. Another commenter also supported the technical correction to CPT code 65780 and stated that it was appropriate to update the work time public use file to reflect 35 minutes of intraservice time.

Response: We appreciate the support from the commenters for our proposals.

Comment: Several commenters stated that CMS assigned a PC/TC indicator of "5" (incident to) for CPT Code 38228 (*Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*) when it was finalized in the CY 2025 PFS final rule. The commenters stated that CPT Code 38228 is not an incident to service, as the physician personally supervises the initiation of the product infusion and is present for the first 15 to 30 minutes. The commenters identified this as a potential technical error and recommended that CMS update the PC/TC indicator for CPT code 38228 from a "5" to a "0" to appropriately capture the nature of the service and to align it with other similar services such as CPT codes 38240 and 38242.

Response: We appreciate the feedback from the commenters and, after reviewing the subject, we agree that this appears to be an unintended technical error. We are therefore finalizing a change in the PC/TC indicator for CPT code 38228 from "5" to "0" for CY 2026.

Comment: A commenter stated that CMS may have inadvertently removed RVUs associated with CPT code 62287 (*Decompression percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar*). The commenter recommended CMS to restore the RVUs associated with CPT code 62287 as non-CMS patients receive the procedure regularly, and many private payers benchmark their physician fee schedules against Medicare.

Response: CPT code 62287 was listed in the RUC recommendations as being scheduled for deletion by the CPT Editorial Panel starting in CY 2026 due to low utilization. However, as identified by the commenter, the CPT Editorial Panel later removed CPT code 62287 from the deletion list and instead revised its descriptor. We will update our ratesetting files accordingly to indicate that CPT code 62287 will remain in active use for CY 2026.

Comment: A commenter stated that CMS revised the Medically Unlikely Edit (MUE) for HCPCS code G0465 from "1" to "2" in April 2025, acknowledging that when multiple blood-derived wound care

treatments are needed in one session, the administration, dressing, phlebotomy centrifugation, mixing, etc. must be performed multiple times, and multiple treatment kits are required. The commenter stated that HCPCS code G0465 is subject to a Multiple Procedure (MPPR) indicator of “2” under which payment is generally based on the 100 percent of the highest valued procedure and 50 percent of the fee schedule amount for the remaining billed procedures. The commenter stated that this indicator is designed to reflect efficiencies that typically occur in either the PE or professional work or both when services are furnished together, however this rationale was not supported for HCPCS code G0465 since over 90 percent of the valuation for the code is based on PE, which is in turn almost wholly based on the cost for the blood-derived wound care treatment kits used in the procedure. The commenter recommended CMS to remove the MPPR by changing the Multiple Procedure indicator from "2" to "0", which would align payment with the corresponding change in the MUE and reflect the clinical resources necessary to provide care using blood-derived wound care treatments.

Response: We appreciate the additional information supplied by the commenter, however we continue to believe that HCPCS code G0465 has been appropriately assigned a Multiple Procedure indicator of “2”. HCPCS code G0465 is not unique in having approximately 90 percent of its valuation based in PE, and there are several dozen other such codes which follow this pattern while also having a Multiple Procedure indicator of “2” (such as CPT codes 19105, 27278, 33285, 47538, 55874, and HCPCS codes 0446T and 0448T). If the commenter has reason to believe that HCPCS code G0465 is potentially misvalued, we encourage them to consider once again formally nominating the procedure under the misvalued code process.

Comment: Several commenters stated that CPT codes 76017, 76018, and 76019 were recommended by both the CPT Editorial Panel and the RUC to be modifier -51 exempt. The commenters stated that to be consistent with other modifier -51 exempt codes, the multiple procedure indicator (MPPR) for these codes should be updated to “0” while the diagnostic imaging family indicator should be updated to “99”.

Response: We continue to believe that the indicators are appropriately assigned for CPT codes 76017, 76018, and 76019, which currently have a value of “4” for the MPPR indicator and “88” for the diagnostic imaging family indicator. The indicators for these codes were based on CPT codes 74183 and

75557, similar magnetic resonance imaging procedures that the RUC recommended as source codes in the utilization crosswalk. The current indicators for CPT codes 76017, 76018, and 76019 represent the standard assignments for MR procedures, and as such we are not finalizing any changes to these codes.

After consideration of the public comments, we are finalizing these technical corrections as proposed along with the modifications noted above in response to comments.

5. Development of Strategies for Updates to Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rule, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113, November 29, 1999) (BBRA) directed the Secretary to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. BBRA required us to establish criteria for accepting supplemental survey

data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we refer readers to discussions in the CY 2011 PFS through 2014 PFS final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA PPIS data for certain specialties (76 FR 73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule,

we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we refer readers to our discussions in final rules for CY 2016 PFS through 2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment on strategies to update PE data collection and methodology (87 FR 69429 through 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that may affect or factor into PE calculations. As described in previous rulemaking, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology currently relies on AMA PPIS data, which we have maintained represented the best aggregated available source of information at the time of its implementation. We noted in our CY 2023 and CY 2024 rules that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

b. Refreshed Data and Request for Information on Timing to Effectuate Routine Updates

In the CY 2024 PFS proposed rule, we continued to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Considering our ratesetting methodology and prior experiences implementing new data, we issued a follow-up from the CY 2023 PFS comment solicitation for general information. We solicited comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current

methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and practitioner types. We also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In response to the CY 2024 RFI, most commenters stated that CMS should defer significant changes until the AMA PPIS results become available. For further background, refer to 88 FR 78841 through 78843. In responding to our RFI, the AMA RUC provided a set of responses, which many other commenters echoed in separate comments. In summary, the AMA RUC letter submission from CY 2024 PFS suggested that CMS should not consider further changes until PPIS data collection and analysis is complete. Overall, the AMA comments generally do not support any change to the methodology and stated that CMS should wait to consider any further changes until PPIS updates become available. Further, we noted that through its contractor, Mathematica, the AMA secured an endorsement for the PPIS updates from each State society, national medical specialty society, and others prior to fielding the survey (88 FR 78843). Refer to the AMA's summary of the PPIS, available at *https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf*. The AMA stated that it expects analysis, reporting, and documentation to be completed by the end of CY 2024 and would share data with CMS when results become available.

Some commenters did not recommend that CMS defer significant changes until the AMA PPIS results become available. These commenters stated that reliance on the PPIS updates may not improve the accuracy and stability of the PE methodology because of the survey design, possible implementation challenges, and a possible lack of transparency or granularity in resulting datasets. Other commenters stated that dependence on the PPIS or survey data in general, due to timing and frequency constraints, may continue to jeopardize independent practice and discourage fair competition among suppliers and providers of services paid under the PFS. These commenters stated that if current trends continue, it will result in far fewer independent practices and more consolidation before the availability of updated survey

data, undermining the sampling methodology of any survey and the general goals of our PE methodology updates.

As we stated in the CY 2025 PFS proposed rule (89 FR 61614), we believe the AMA's approach may possibly mitigate nonresponse bias, which created challenges using previous PPIS data. However, we remain uncertain about whether endorsements prior to fielding the survey may inject other types of bias in the validity and reliability of the information collected. We believe it remains important to reflect on the challenges with our current methodology, and to continue to consider alternatives that improve the stability and accuracy of our overall PE methodology. We reiterate our discussion summarizing the responses to previous years' RFIs in each of the CY 2023 PFS and CY 2024 PFS final rules (refer to 87 FR 69429 through 69432 and 88 FR 78841 to 78843). We also requested general information from the public on ways that CMS may continue to work to improve the stability and predictability of any future updates. Specifically, we requested feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs. We stated that we believe that establishing a cycle of timing to update supply and equipment cost inputs every 4 years may be one means of advancing shared goals of stability and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and propose a phase-in period over the following 4 years. The phase-in approach maps to our experience with previous updates. Additionally, we stated that more frequent updates may have the unintended consequence of disproportionate effects of various supplies and equipment that have newly updated costs.

Further, we solicited feedback in the CY 2025 proposed rule RFI (89 FR 61614) on possible mechanisms to establish a balance whereby our methodology would account for inflation and deflation in supply and equipment costs. We stated that we remain uncertain how economies of scale (meaning a general principle that cost per unit of production decreases as the scale of production increases) should or should not factor into future adjustments to our methodology. We stated that there remains a diversity of perspectives among interested parties about such effects. We sought information about specific mechanisms that may be appropriate, and in particular, approaches that would leverage verifiable and independent third-party data that is not managed or controlled by active market participants.

In response to our CY 2025 proposed rule RFI (89 FR 97737), numerous commenters expressed concerns regarding CMS' current PE methodology, particularly highlighting its perceived inadequacies in accommodating modern medical technologies and services, such as Software as a Service (SaaS) and artificial intelligence (AI). These commenters stated that there is a need for CMS to revise its PE methodology to better reflect the actual costs of running medical practices today, which includes more frequent updates and the incorporation of direct costs for software and innovative technologies. Many also supported the AMA's PPIS efforts to ensure updated and accurate data informs PE calculations. The commenters recommended CMS to collaborate closely with medical associations and incorporate broad interested parties feedback without increasing reporting burdens, particularly for smaller practices.

We note that we have an ongoing contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. We will continue to study possible alternatives and have included analysis of the updated PPI and CPI Survey data in the proposed rule, as part of our ongoing work.

As previously stated in this section and discussed in sections II.N. and VI. of the proposed rule, we acknowledge that, at the time of publication of the proposed rule, the AMA concluded their data collection efforts and submitted the data to CMS for us to consider implementing the PE/HR data and cost shares in PFS ratesetting for CY 2026. In the current system, accurate measurement of the indirect to direct PE ratio and the PE/HR for each specialty is critical to ensure that allocated indirect PE RVUs (and therefore total PE RVUs) accurately estimate service-level PE as defined by PFS ratesetting steps described previously in this section. Because the PE methodology is budget neutral, inaccuracies in the PE/HR data for some specialties can significantly impact the overall pool of PE available to distribute across all services, and therefore overall valuation and payment.

We appreciate the AMA’s PPI and CPI Survey data collection efforts, and recognize the significant costs incurred to collect the data. However, our initial review of the new data raises substantive concerns about their accuracy, utility, and suitability as an immediate replacement for the current PE/HR data and cost shares for use in allocating nearly $91 billion in payments across PFS services. These concerns relate to issues including:

- *Low Response Rates and Representativeness*: A primary concern is the low response rate of the surveys. The 2024 PPI Survey had a response rate of 3 to 7 percent, depending on whether practices that did not click through the invitation email link were counted as non-respondents. The CPI Survey had a slightly higher response rate between 7 to 9 percent. In comparison, the 2008 PPIS had a response rate of 12 percent. Low response rates raise concerns as to whether responding practices are systematically different from sampled practices that did not or could not respond. Additionally, in response to lower-than-expected response rates, the AMA allowed 102 practices to volunteer to participate in the survey. Although most of these volunteer practices did not complete the survey, allowing practices to volunteer data adds to concerns about the representativeness of the data.

Additionally, the 2008 PE/HR estimates were based on the observations (about half of responses) that had no missing expense data, whereas the 2024 PE/HR estimates and the shares are based on observations that had at least some non-missing data where the missing data was imputed as described in the Survey Methods Report (Step 6)[1]. It should be noted that some expense categories were reported more consistently by survey respondents. For example, 97 percent of the respondents reported compensation (physician work) compared to only 69 percent that were able to report non-billable drugs (direct expense under supplies) and information technology (indirect expense). Similarly, many survey respondents were not able to separately report expenses for qualified health providers (QHPs). Nearly 40 percent of the responses used in the calculation of the PE/HR estimates reported that they had nurse practitioners or physician assistants in their practice, but only 27 percent were able to separately report non-physician compensation expenses.

- *Small Sample Sizes and Sampling Variation*: Due in part to the low response rates, the number of respondents was small for many specialties included in the 2024 PPI and CPI data. For example, the PE/HR measures for Vascular Surgery are based upon responses from only 20 practices. Moreover, the PPI and CPI survey estimates give more weight to responses from practice types that would otherwise be under-represented in the sample, relative to the population of all eligible practices in a given specialty. For example, such an adjustment would be applied if the sample contained a higher proportion of facility-based practices than there are in the full population of practices in a given specialty. Applying such

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[1] https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf.

weights generally results in estimates that are less precise than an unweighted sample of a given size. One way to quantify this is via the effective sample size, which estimates the sample size from an unweighted sample that would be required to produce survey estimates that are as precise as those from the weighted sample. The effective sample size can be estimated as the ratio of the sample size to the design effect, which is reported in the PPI/CPI Methods Reports[2, 3]. For Vascular Surgery, the reported design effect is 1.82, meaning that the 20 observations correspond to an effective sample size of only 11 (calculated as 11.0=20/1.82). For 12 of 18 broad specialty groupings reported in the 2024 PPI Survey, the effective sample size is less than 18.0 and for four of these specialties the effective sample size is less than 10.0. Similarly, in the CPI Survey data, the effective sample sizes are also small, with all but one below 20.0, and as low as 6.2 for Oral Surgery. Not including practices that volunteered, only 327 sampled practices completed the 2024 PPI Survey compared to 3,088 anticipated completions.

The low sample sizes contribute to substantial statistical uncertainty regarding the true specialty-level PE/HR measures. Figure A-B1 illustrates the 95 percent confidence intervals for direct and indirect PE/HR as reported in the 2024 PPI/CPI Surveys. The large points represent the new PE/HR estimates, the bars indicate the confidence intervals, and the smaller points show the current PE/HR estimates used in PFS ratesetting from the 2008 PPIS. The 2024 CPI and PPI Survey confidence intervals are so broad that they cover most of the original 2008 PPI PE/HR values in nominal dollars (that is, not adjusted for inflation). Therefore, in most cases, the new data are unable to establish statistically significant changes from the status quo, especially since the old PE/HR measures were themselves estimated with substantial levels of statistical uncertainty. Even so, the new PE/HR estimates differ enough from the old ones that many specialty-level impacts of adopting the new data are quite large. When translated into RVUs, the PE/HR standard errors for specialties such as Cardiology, Pathology, Ophthalmology, and Vascular Surgery correspond to a wide range of payments for services provided by those specialties meaning that the new data are compatible with a wide range of specialty impacts for many specialties.

- *Lack of Comparability to Previous Survey Data:* The 2024 PPI and CPI Survey data groups specialties in a considerably different way from the current structure, with 29 specialty groupings

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[2] https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf.
[3] https://www.ama-assn.org/system/files/cpi-survey-methods-report-main-report.pdf.

compared to 51 in the 2008 data. We found that using the 2008 PE/HR data averaged within the 2024 PPI Survey specialty groupings would lead to large specialty-level impacts in some cases, further complicating comparisons between the old and new data and indicating that the new 2024 specialty groupings is impactful on redistribution among the PFS alone. We refer readers to section VI. of the proposed rule for discussion of the impacts of the 2024 PPI Survey specialty groupings on PFS ratesetting. It is also unclear why some specialties were collapsed into relatively broad groups for the purposes of data collection and reporting while others were not.

- *Potential Measurement Error*: We are concerned that sampled practices were not able to accurately report the data necessary to respond to the PPI and CPI Surveys. For example, the survey contractor found that practices frequently had challenges reporting the number of physicians working in the practice. One may expect that the number of physicians in a practice is relatively easier for practices to measure than some of the specific costs integral to reporting PE/HR. However, the contractor noted that – prior to an adjustment – their estimate of the total number of physicians was nearly three times as large as the number of physicians in their sampling frame which "indicated a large potential for measurement error in this estimate."[4] Also, because information on the number of physicians in each practice was available from external data which were obtained before survey data were collected, to inform the survey design, we believe it is likely that the number of physicians was highlighted as having high potential measurement error because it was possible to compare this measure against external data. Moreover, some responding practices reported that it took more than 40 hours to complete the survey, which suggests that the required data are not readily captured by their accounting systems and therefore may not be fully reliable.

Thus, we are left with doubts about not just the amount of data collected, but its quality as well.

- *Missing and Incomplete Data Submission*: The PPI Survey summary data was submitted to CMS in January 2025 and the CPI Survey summary data in February 2025. These initial submissions were missing from many of the elements required to analyze the data and determine their usability in our PE methodology. We inquired about these elements and have since received some additional information, but some of the information was not available due to the survey contract concluding, such as estimates

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[4] https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf.

based solely on the survey responses that had no missing expense data or the impact of the trims and edits of the data described in the PPI Survey Methods Report. Additionally, some data is completely missing from the submission, therefore we had to utilize old PE/HR data in analyses for specialties such as Independent Diagnostic Testing Facilities (IDTFs) when developing models to incorporate the data. Additionally, the American Occupational Therapists Association (AOTA) requested the continued crosswalk of PE/HR data from Physical Therapy to Occupational Therapy because the CPI respondents may have indirectly reported the salaries of occupational therapy assistants with provider compensation rather than including their salaries in clinical staff compensation.

Additionally, there is summary data provided from the PPI Survey[5] that are not provided for the CPI Survey[6]. For example, the PPI Survey summary data include two lines – "MEI shares" and "All [specialties]" – that could presumably be used to establish the share of total RVUs that should be attributed to work, practice expense, and malpractice, but we do not believe that they reflect the specialties' data from the CPI Survey, even though those specialties are included in PFS ratesetting, account for a significant portion of the PFS PE RVU pool, and draw from the same pool of RVUs as the PPI Survey specialties. Similarly, we do not have the corresponding CPI Survey specialty weighting information provided to CMS for the PPI Survey specialties, therefore, we have limited information to develop an approach for calculating shares for all CMS specialties accounted for in both the PPI and CPI Surveys.

In an effort to incorporate PPI and CPI Survey specialties' data despite the lack of analogous summary data, we developed possible methods to weight the data for all CMS specialties in a cohesive manner for use in the PFS PE methodology such as estimates of total RVUs and total service time by specialty used for CY 2026 PFS ratesetting. We refer readers to section VI. of the proposed rule for discussion of the different weighting methodologies and their resulting shares of work, PE, and MP.

Overall, the small sample sizes and the apparent presence of high levels of measurement error in data elements that could be compared to external estimates suggest that specialty-level PE/HR measures may be challenging to measure reliably through voluntary surveys alone. We note that the interested

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[5] https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.
[6] https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.

parties may concur with this statement based on the Methods Report, which states considerations for future data collection efforts that may forego the survey structure and rely on other practice expense sources such as tax returns. We believe that a more efficient and transparent system that could be updated on a regular basis may be possible using available administrative data (such as Medicare claims; hospital cost reports; publicly-reported tax information such as from IRS Form 990; and data collected by other agencies, such as the Census Bureau's Service Annual Survey (SAS)) to the fullest extent possible and relying on survey data only to fill gaps only where available data do not exist. An alternative to collecting any survey data would be to modify the PE allocation system so that it only relies only on data that can be measured accurately and on an on-going basis. For example, if there are components of indirect PE that are not captured in administrative data, those expense categories could potentially be re-classified as direct costs and accounted for in a manner similar to how direct costs are currently considered.

Beyond the use of the data in our PE methodology, we need information on the total share of PFS payments that should be allocated for work, PE, and MP. Data collected in the 2024 PPI and CPI Surveys could be used for this purpose, as well as potentially be considered in a construction of the MEI in the future; however, there still remain underlying concerns with the sample representativeness for these purposes. The AMA has stated that shares derived from data collected from the Service Annual Survey (SAS) for the 2017-based MEI miss many physicians who work in facility settings and thereby understate the percent of total PFS payments that should be allocated to physician work. The data needed to derive the three component shares (work, PE, and MP) are more aggregated than the specialty-level PE/HR data required for the PE methodology, so we have fewer concerns with the small sample sizes for this application. However, we continue to have similar concerns with the data related to measurement error and sample representativeness for purposes of the shares.

Figure A-B1: COMPARISON OF PE/HR DATA FROM 2008 PPIS AND 2024 PPI AND CPI SURVEY WITH 95 PERCENT CONFIDENCE INTERVALS FOR THE 2024 DATA

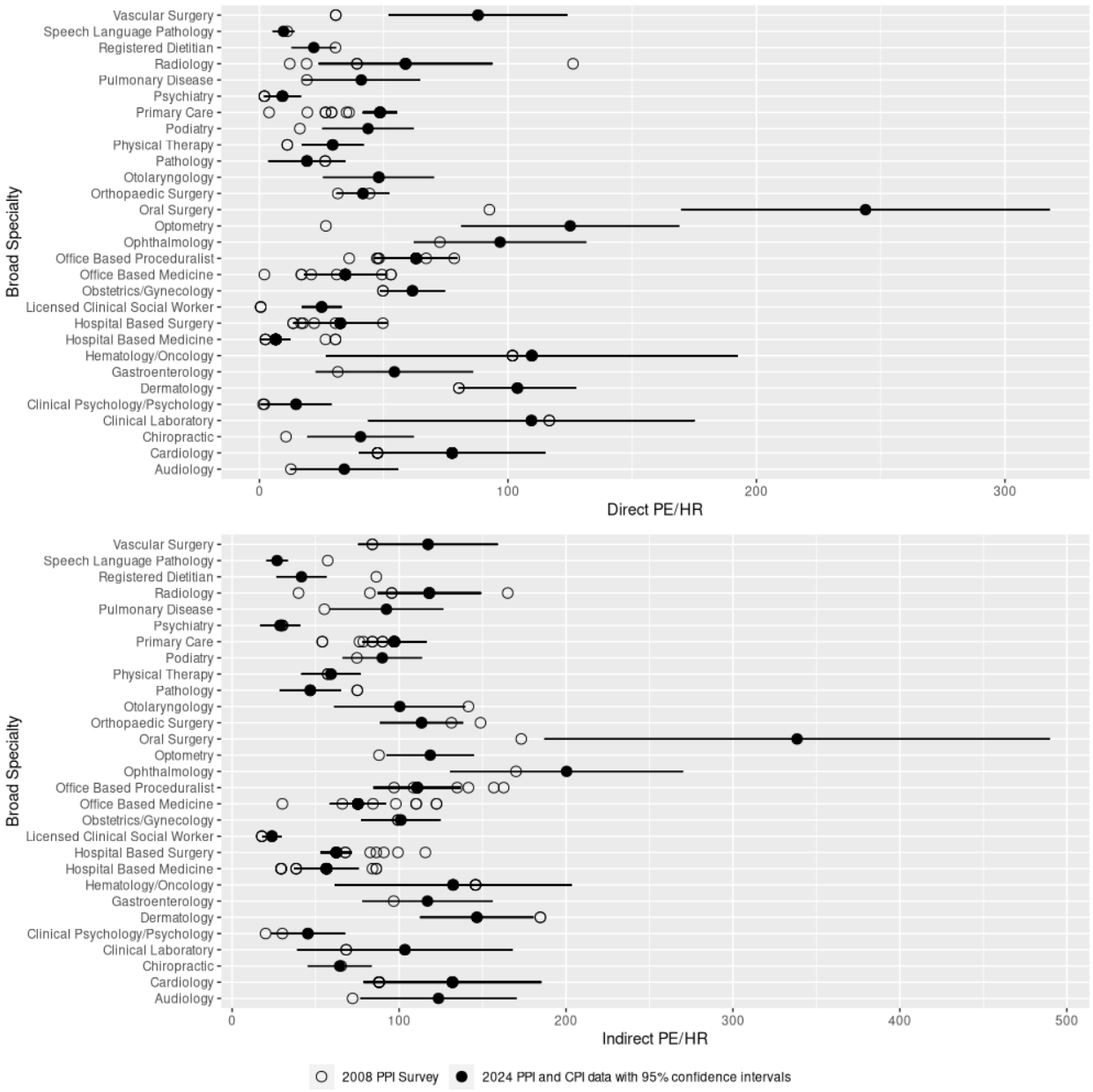

Figure A_B1: Comparison of PE/HR data from 2008 PPI Survey (small, hollow dots) and data from the 2024 PPI and CPI Survey (large, filled dots) with 95 percent confidence intervals for the 2024 data. Data are grouped by the 2024 specialty groupings.

At the time of the publication of CY 2026 PFS proposed rule (90 FR 32593 through 32597), we continue to conduct ongoing analyses on the potential impact of the AMA's PPI and CPI Survey data on PFS ratesetting. Due to overarching concerns with the data described earlier and our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through routine updates to the MEI, we reiterate that we proposed not to implement the PE/HR data or cost shares from the AMA's survey data at this time, and proposed instead to maintain the current PE/HR data and

cost shares for CY 2026 PFS (90 FR 32593) ratesetting. At the same time, we remain focused on proposals that reflect evolutions in practice, including the site of service payment differential discussed later in this section, while we continue to hold strong interest in specialty-level practice expense updates. Consequently, we intend to work with interested parties, including the AMA, to understand whether and how such data should be used in PFS ratesetting in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters opposed CMS' decision to continue using 18-year-old survey data from 2007, stating that it no longer reflects current healthcare practice costs. Additionally, many commenters expressed concern about CMS' proposal to delay implementation of the PPI Survey data for CY 2026, emphasizing that reliance on outdated data undermines CMS' stated goal of improving payment accuracy and ignores the reality that the healthcare system has fundamentally changed over the past two decades.

The commenters highlighted significant methodological improvements in the 2024 survey that make it superior to the 2007 approach. Commenters stated that the 2024 PPI Survey represented a fundamental shift from individual physician-level data collection to practice-level data collection, encompassing 18,086 physicians across 831 departments in 380 practices compared to the original 2,795 individual physicians surveyed in 2007. Commenters stated that this change emphasized practice attributes such as size, ownership, and care delivery settings rather than individual physician characteristics, reflecting the evolution of healthcare delivery models. Commenters stated that the survey implemented several improvements including better representation through sampling focused on practice characteristics that correlate with practice expense per hour, more sophisticated imputation techniques to address missing data, and the ability to analyze department-level data by specialty.

The commenters recommended that the practice-level approach provides a more accurate representation of modern healthcare delivery. They stated that the survey addressed methodological biases present in the 2007 data, where MEI shares were skewed toward practices with higher expense levels, and provided data for all physicians rather than just those reporting expenses at the individual level. Many commenters emphasized that continuing to use 18-year-old data systematically undervalues

current practice costs while ignoring significant changes in healthcare infrastructure, including substantial new information technology expenses.

Addressing response rates, a commenter stated that approach used to calculate the 7 percent response rate “was equivalent to the American Association of Public Opinion Research (AAPOR) standard response rate calculation" as it relates to whether delivered but unopened email invitations should be included in the denominator of the response rates. A commenter stated that non-reporting of specific data requested by the PPI Survey “indicates that practices often do not organize their financial data in a way that easily translates to the methodology underlying the physician payment schedule.” We agree with this point and believe that this indicates that it may be necessary to implement a change in the PFS ratesetting so that it only requires input that can be measured reliably.

The commenters suggested that there was concrete evidence demonstrating substantial cost changes over time. They emphasized that the 2024 survey revealed important cost trends, with overall direct practice expense per hour increasing by almost 40 percent from 2007 while indirect expenses only increased by 5 percent, providing valuable insights into specific expense category changes that reflect the reality of contemporary medical practice and justify the need for updated payment methodologies. A commenter requested that CMS convene listening sessions to validate and incorporate the 2024 PPI data and ensure the methodology is fully vetted, transparent, and reflective of real-world practice.

Several commenters supported CMS' cautious approach, with some expressing concerns about inappropriate specialty grouping that combined unrelated specialties in a category called "Office Based Proceduralists" despite having no meaningful correlation in practice economics. A commenter stated that the payment rates resulting from the use of this combined category would be "disastrous for practices' financial sustainability and patient access to care" and expressed appreciation for CMS' decision to maintain current data while working toward better methodological approaches. A commenter requested that CMS phase in any future implementation of revisions to the practice expense methodology or inputs.

Response: Regardless of how many physicians are members of the responding practices, the new PE/HR estimates and standard errors are compatible with a wide range of true underlying PE/HR measures. According to our calculations, the survey data cannot rule out PE/HR values that would imply a range of at least 10 percentage points of specialty-level impacts for 22 of 56 specialties, when measured

through 95 percent confidence intervals. While we agree that the purpose of new data is not to test changes in underlying PE/HR measures, utilizing the PPI data would mean, in some cases, changing a specialty's total PFS payments by 10 percentage points or more based on data that cannot rule out PE/HR values consistent with no underlying change.

These assessments of sampling variation all assume no selection bias or measurement error. While we agree that the survey design itself is an improvement over the 2007 PPI Survey in terms of weighting for practice characteristics, we believe there still is substantial risk of measurement error. As an example, physician headcounts were the one survey data element that could be externally validated, and it appears to be the case that those data were substantially misreported. In its report to the RUC, Mathematica indicates that "the total number of physicians was estimated to be 2,056,784, nearly three times larger than the total number of physicians from the two sample frames, which was 693,502."[7] The inaccuracy in the data of the one survey element that could be externally validated raises concerns about the quality of data elements that cannot be externally validated.

Regarding the AAPOR response rate, we note that AAPOR publishes six definitions for the response rate. The version that the commenters reference as the "most-common AAPOR response rate" uses an estimate of the proportion of unknown eligibility cases that would, in fact, be eligible. The assumption by the RUC and its contractor, Mathematica, that none of the emails that were delivered but left unopened were for eligible practices results in an "upper bound" response rate, not the "most common" rate. Nonetheless, our primary concern is with the total number of responses that the data collection effort produced. Against a planned 3,188 responses, only 380 were obtained. This low survey yield means that even after grouping many specialties together, the estimates are still highly exposed to sampling variation.

Regarding the perceived biases of the 2007 methodology toward the expense allocation of practices with higher levels of expenses (even if they had the same number of physicians who worked the same number of hours as in practices with lower levels of expenses), we note that, as. it relates to the PFS, the MEI is used to establish the size of the pools of work, PE, and MP. Because specialties that have higher expense levels also receive a larger share of total PFS payments, data from high-expense

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[7] https://www.ama-assn.org/system/files/ppi-survey-methods-report.pdf, *page 37*

specialties should have greater influence on the pools than data from low-expense specialties, when measured on a per-physician basis. In summary, the MEI should produce a sensible split of total PFS dollars between work, MP, and MP. This is done by aggregating total expenses across practices, not by averaging shares at the physician level.

After consideration of the comments we received, we are finalizing our proposal not to implement the PE/HR data or cost shares from the AMA's survey data at this time, and to maintain the current PE/HR data and cost shares for CY 2026 PFS ratesetting. We remain interested in further information that could help inform updates to the PE/HR data or cost shares through future rulemaking.

c. Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential

While we proposed not to incorporate the PPI and CPI Survey data into PFS ratesetting for CY 2026, we proposed a significant refinement to our PE methodology to better reflect trends in physician practice settings. As detailed previously in the description of the practice expense methodology, many services have a site of service payment differential between the facility (F) and non-facility (NF) settings under the PFS. Services furnished in the non-facility setting, such as a physician's office, include the physician work RVUs, direct costs for supplies, clinical staff, and equipment, and indirect costs allocated based on the direct costs and the greater of either the clinical labor costs or the physician work RVUs. In the facility setting, the payment rate includes physician work RVUs and the indirect practice expense allocated based on the physician work RVU. The direct costs in the facility setting are paid under a different payment system than the PFS, such as the OPPS. Indirect costs allocated to services furnished in the facility setting are meant to reflect the typical costs associated with practice expenses in that setting of care.

In the decades since implementing the PE methodology, there have been significant transformations to the landscape of the healthcare delivery system in the United States, particularly regarding physician practice patterns. Historically, private practice was the dominant model for physicians, offering them autonomy, flexibility, and the opportunity to build independent practices. Specifically, in 1988, approximately 72 percent of physicians were full or part owners in their practice[8].

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[8] Kane CK. Emmons, DW. New data on physician practice arrangements: private practice remains strong despite shifts toward hospital employment. Chicago (IL): American Medical Association; 2013. Policy Research Perspective 2013-2.

This percentage had dropped to 35.4 percent by 2024, representing a 52 percent decrease, with a corresponding rise in physicians in hospital-owned practices and physicians employed directly by a hospital. The percentage of physicians in hospital-owned practices has increased by over 47 percent, from 23.4 percent in 2012 to 34.5 percent in 2024. Similarly, 12.2 percent of physicians were employed directly by a hospital (or contracted directly with a hospital) in 2024, up from 5.6 percent in 2012[9]. In their June 2025 Report to Congress[10], MedPAC notes that there are 9 specialties where 60 percent of the clinicians who billed Medicare furnished 90 percent or more of their services in the facility setting. These trends indicate a steady decline in the percentage of physicians working in private practice, with a corresponding rise in physician employment by hospitals; and growth in the percentage of physicians who practice exclusively, or almost exclusively, in the facility setting. When the PFS was established, the methodology for allocating indirect practice expense was based in part on an assumption that the physician maintained an office-based practice even when also practicing in a facility setting. In that context, the PE methodology has allocated the same amount of indirect costs per work RVU, without regard to setting of care.

We note that, in the AMA's comment letter on the CY 2023 PFS proposed rule[11], they stated that physician practices maintain some indirect practice expense costs for physicians who are solely facility-based such as coding, billing, and scheduling. We acknowledge that these indirect costs should be accounted for in PFS payment through PE RVUs, but we believe that allocating the same amount of indirect practice expense based on work RVUs in both settings may overstate the range of indirect costs incurred by facility-based physicians if it is now less likely that they would maintain an office-based practice separate from their facility practice. In a 2018 report developed under contract with CMS, RAND noted that "operating from the perspective of paying for the 'typical' instance of a procedure, these analyses suggest that the current system could be improved by shifting more of the allocation of PE RVUs to the physician office setting"[12]. As MedPAC notes in their June 2025 report, "In cases when

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[9] Kane CK. Physician Practice Characteristics in 2024: Private Practices Account for Less Than Half of Physicians in Most Specialties. American Medical Association.
[10] MedPAC. (2025). June 2025 Report to the Congress: Medicare Payment Policy. Chapter 1 Reforming physician fee schedule updates and improving the accuracy of relative payment rates. https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_MedPAC_Report_To_Congress_SEC.pdf.
[11] https://downloads.regulations.gov/CMS-2023-0121-2694/attachment_1.pdf.
[12] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. https://www.rand.org/pubs/research_reports/RR2166.html.

clinicians practice exclusively or almost exclusively in a facility, or where a facility is financing indirect PE for clinicians, payment to both entities for indirect PE costs may be duplicative and unnecessary". While the relative relationship between the PE allocated to services furnished in a facility and non-facility setting may have been more reflective of the actual expenses incurred by physicians when the PE methodology was originally established, maintenance of that element of the methodology in the face of changing practice patterns likely represents an imbalance of the practice expense allocated to the facility relative to the non-facility. Within the PFS relative value system, any overstatement of practice expenses in the facility setting would affect the allocation of indirect costs in the non-facility setting. This dynamic, in which relative resources involved in furnishing PFS services may not be adequately reflected in facility and non-facility settings, has the potential to contribute to broader undesirable financial incentives toward higher-priced settings of care, like hospitals, and away from more efficient settings, like physician offices [13, 14, 15]. This could result in unnecessary costs for payers and beneficiaries, and obstacles to physicians and other professionals operating independent practices.

We share MedPAC's concerns regarding the potential for duplicative payment under the current PE methodology for allocating indirect costs for physicians practicing in the facility setting. Allocating the same amount of indirect PE per work RVU for services furnished in the facility setting as the non-facility setting may no longer reflect contemporary physician practice trends. As we noted in the proposed rule, data suggests that fewer than half of physicians currently own their practices, but the underlying assumption embedded in the PFS payment methodology presumed that physicians generally maintained office practices (and incurred associated indirect costs) even when they furnished care in facility settings. For these reasons, for each service valued in the facility setting under the PFS, we proposed to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs beginning in CY 2026. This change will occur in step 8 of the PE RVU Methodology described earlier in this section, in which indirect allocators (direct costs, clinical labor, and work RVUs) are assigned. For example, the work RVU for CPT code 33533 (*Coronary artery bypass, using arterial*

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[13] https://pmc.ncbi.nlm.nih.gov/articles/PMC4191490/#:~:text=Using%20generally%20accepted%20accounting%20practices,to%20more%20intense%20resource%20use.
[14] https://healthcostinstitute.org/hcci-originals-dropdown/all-hcci-reports/shifting-care-office-to-outpatient.
[15] https://www.bcbs.com/dA/392da3b5a7/fileAsset/BHI%20Issue%20Brief%20December_121323_SiteNeutral.pdf.

graft(s); single arterial graft) is 33.75. For CY 2025, using the full work RVU as an indirect allocator, CPT code 33533 had approximately 12 indirect PE RVUs. Under this change to the methodology, where we will reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs, CPT code 33533 would have approximately 7.2 indirect PE RVUs.

We noted in the proposed rule that this change to the indirect cost allocation methodology is intended to better recognize the relative resources involved in furnishing services paid under the PFS in facility and non-facility settings. We compare this change to our current methodology, which functionally presumes approximately equal indirect costs incurred by physicians across sites of service. This presumption was initially made in the context of most practitioners maintaining office practices independent of the facilities in which they provided care, and as we discussed in the proposed rule, appears to be inconsistent with contemporary trends in physician practice. We understand from the AMA's comment letter on the CY 2023 PFS proposed rule noted earlier that physician practices may incur some indirect PE costs (such as coding, billing, and scheduling) for physicians who are facility-based. To better inform our consideration of how to account for any such costs in the PE RVU methodology, we sought comment on the specific types and magnitude of indirect PE costs incurred that are attributable to physicians who practice in part or exclusively in a facility setting, and any variables that affect whether and to what extent a practice would incur them. We also sought comments on whether our proposal to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs is an appropriate reduction or whether we should consider a different percentage reduction for CY 2026 or in future years. While our change to the methodology represents a starting point to correcting potential historic distortions in the allocation of indirect PE costs across settings of care, we intend to further examine our methodology and consider additional refinements based upon public comments received and any studies or data sources identified. We solicited comments on whether there are additional data sources that might help identify a more precise site of service difference in the allocation of indirect PE RVUs. We believe the implementation of this update will more accurately account for the resource costs involved in physicians furnishing care across all settings and correct potential distortions in the allocation of indirect PE under our current methodology. We refer readers to section VI. of the proposed rule for discussion of the impacts of this proposal on CY 2026 PFS

ratesetting.

We specifically solicited comments on whether and how this policy should apply to codes with MMM global periods (maternity services) and how it could specifically impact access to maternity services, given our understanding that many of the patient encounters across those services occur in the office setting. As we noted in the CY 2024 PFS final rule (88 FR 78949), maternity services are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, which include a relatively large number of E/M visits performed along with delivery services and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method. Given that the work RVUs for maternity services encompass significant care during this lengthy period that may be furnished in the non-facility setting, we also solicited comment on whether we should include these services in our policy to reduce the allocation of PE based on work in the facility setting.

We requested comments on all aspects of this proposal, including ways to improve the allocation of facility and non-facility PE RVUs in the future. We also solicited comments on alternative approaches to improving the allocation of indirect PE as outlined in Chapter 1 of MedPAC's June 2025 Report to the Congress (pages 27 through 33).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters strongly supported CMS' proposal. These supporters indicated that the proposed change increases the accuracy of the PFS and/or advances site-neutral payments. These commenters applauded CMS' efforts to align payments between sites of care, stating that payment differentials by site of care increase costs without accompanying quality improvements. The commenters also noted that overall pay differences between hospital outpatient departments and physician offices for the same services put independent practices at a competitive disadvantage. Some commenters suggested that CMS should reduce the allocation further, allocating only one third of the indirect PE from the work RVU in developing PE RVUs, given that only 35.4 percent of physicians own their own practice.

Response: We appreciate these comments on the proposal. We agree that updating these assumptions will improve the accuracy of the RVUs assigned to different settings of care. We also

recognize that reducing unnecessary or unwarranted payment differences across settings of care would likely have significant benefits in leveling the playing field. We appreciate commenters' interest in reducing the allocation of indirect PE RVUs beyond the proposal for the reasons the commenter suggested. We note that we will continue to seek and be open to information regarding how to refine the allocation methodologies in future notice and comment rulemaking.

Comment: Several commenters opposed the proposal. Some of these commenters stated that the proposal lacks face validity and is based on arbitrary assumptions rather than empirical data. The commenters stated that CMS should explore more sophisticated methodologies, grounded in actual cost data and reflecting real-world complexity of physician practice arrangements, rather than implementing the proposed blanket reduction approach that relies on broad generalizations. Many commenters requested that if CMS does implement this proposal, it allocates 75 percent of the indirect PE based on the work RVUs, and/or that the proposal be phased in over 3 to 4 years. Some of these commenters noted that PE changes of similar magnitude have historically been implemented over several years, such as clinical labor pricing adjustments and supply/package corrections. A commenter stated that CMS declined to adopt the 2024 AMA PPI survey data due to representativeness concerns yet simultaneously proposed sweeping methodological changes that also haven't been validated. Multiple commenters stated that CMS should not finalize this provision without conducting comprehensive additional data analysis to understand the full implications of the proposed changes.

Response: We appreciate these commenters and their concerns. We acknowledge that the proposal recognizes a change in the underlying assumptions that are made in the PE methodology based on broad changes in the marketplace that have occurred in the three decades since the methodology was originally established. The underlying assumptions in the methodology, both the status quo that assumes no variation whatsoever in indirect costs per work RVU between settings of care and under the proposal that would allocate half the amount of indirect costs, are not driven by precise numbers, and the proposed change will better recognize the relative resources involved in furnishing services paid under the PFS in facility and non-facility settings. We are also eager to consider more precise data to help refine the allocation methodologies for future rulemaking, should such data become available. We also recognize that we have historically phased in some significant changes in PE data and methodology over several

years. However, in the case of this proposed change, we note that we consider our proposal itself to be a tempered one, considering (as other commenters have noted) that significantly fewer than 50 percent of practitioners own their own practice. Furthermore, while a multi-year transition would mean mitigating reductions for facility services, it would also reduce the increases in payment that would otherwise be made for non-facility services. Such a phase-in would perpetuate the overall site of service payment disparities that have clearly contributed to significant distortions in the market where the difference between overall payment for services in facility settings compared to non-facility settings continues to grow.

Comment: Some commenters raised concerns about disproportionate impacts on providers in rural and underserved areas, stating that these providers already face significant challenges in providing specialized care to vulnerable Medicare populations. Other commenters specifically noted that the proposal would improve access, particularly in rural areas, where maintaining independent practices is often the only way patients can access timely treatment. A commenter stated that the lack of comprehensive impact analysis on different geographic regions, practice types, and patient populations represents a significant oversight that could lead to unintended access problems and practice closures in areas where healthcare resources are already scarce.

Response: We share commenters' interest in the care of beneficiaries in rural and underserved areas. We believe that updating the assumptions that underly the methodology will result in more accurate valuation across settings and agree with commenters that improved valuation that better recognizes the costs of care in non-facility settings will be beneficial to many of those that practice in rural communities. We acknowledge that facility-based care can also be an important part of care in rural and underserved communities, and we note CMS' efforts to mitigate risks for rural providers in the context of the OPPS and related policies. For these reasons we remain interested in understanding the impact of PFS payment on both rural providers and physicians and other practitioners. We believe that on balance, this policy will support independent practices, including in rural areas, and that for these practices, it may be all the more urgent that we update the assumptions embedded in the PE methodology to better reflect current practice. We did not receive comments addressing the specific types and magnitude of indirect PE costs incurred that are attributable to physicians who practice in part or exclusively in a facility setting, and any

variables that affect whether and to what extent a practice would incur them. While we received comments suggesting that we should allow a higher percentage for indirect PE allocation based on work RVUs, such as 75 percent, commenters did not provide a justification for this figure. In contrast, commenters that suggested that CMS only allocate one third of the indirect PE allocation based on work RVUs in the facility setting stated that this was justified given that 35.4 percent of physicians own their own practice. As stated in the CY 2026 PFS proposed rule (90 FR 32593), we believe that 50 percent is a conservative estimate of the actual indirect practice expense that should be allocated based on the work RVU. Several commenters acknowledged that they did not have any evidence suggesting that the 50 percent reduction is inaccurate. We note that we, as well as interested parties such as MedPAC, have long been concerned about the allocation of indirect PE in the facility setting given our imperative to establish RVUs that reflect the relative resources involved in furnishing services, and have been developing policy approaches to address this issue for several years. We carefully considered analyses done over several years by MedPAC and RAND and believe this proposal is a relatively measured step toward addressing the overstatement of indirect costs incurred by facility-based physicians.

Comment: Several commenters stated that CMS' fundamental assumptions regarding employed physician costs are disconnected from the reality of modern healthcare practice arrangements. These commenters stated that despite the documented trend toward declining private practice ownership and increasing physician employment by larger health systems, the assumption that employed physicians do not incur significant administrative and overhead costs is incorrect. The commenters stated that physicians providing care in facility settings continue to face substantial indirect costs including coding, billing, scheduling, and administrative overhead, regardless of their employment status. The commenters stated that the AMA's PPI survey data provides a concrete quantification of these costs, with estimates of indirect costs of $57 per hour for hospital-based medicine and $62 per hour for hospital-based surgery. The commenters stated that many hospital-employed physicians operate under arrangements where practice expense costs are charged back to their departments, including rent or leasing space based on square footage used, staffing costs, billing infrastructure, and administrative support. Another commenter noted that some independent medical groups have professional service contracts with hospitals, rather than employment arrangements. The commenters stated that the proposed flat 50 percent reduction to the

work RVU allocator fails to account for these varied arrangements and represents an oversimplified approach to a complex issue. The commenters requested that CMS focus on collecting up-to-date information on the true cost of practicing in facility vs. non-facility settings before assuming differences warrant a 50 percent reduction.

Response: We appreciate these comments, and we acknowledge that practice arrangements vary significantly in current practice. Again, we remain open to more specific data that addresses the variability, as well as feedback on how to update the valuation and payment methodologies to better reflect the relative resources involved in furnishing the services. In the meantime, we continue to believe the underlying assumptions within the methodology should be reasonably grounded in the best information available. We agree with commenters that physicians generally incur indirect costs in the facility setting, and that is why we retained allocating significant amounts of indirect PE RVUs per work RVUs in the facility setting. As some commenters pointed out, in many cases the proposed allocation may still overestimate indirect costs. Under the current methodology, there are only two sites of service where PE RVUs vary (nonfacility and facility). . We believe that the proposed policy more accurately reflects indirect PE in the facility setting compared with the previous assumption that the indirect costs are relatively equal. With respect to comments about the PPI survey data, as detailed in section II.B of this final rule, we are concerned that given the low response rate of the PPI survey data, the indirect cost estimates are not an accurate reflection of the typical indirect PE costs faced by physicians who furnish most of their services in the facility setting.

Comment: A commenter stated that CPT codes with bundled post-operative visits often have follow-up visits performed in a physician office even when surgery is performed in facility settings, and that the proposal does not account for these indirect PEs. The commenter also noted that CMS includes direct PE inputs for several thousand services valued in the facility setting, and these direct costs correlate with indirect costs, stating that the presence of these direct costs indicate that indirect PEs are incurred for services furnished in the facility setting.

Response: We did not propose to change the allocation of indirect costs based on direct costs in the facility setting. Instead we proposed that beginning in CY 2026 we would combine the direct PE inputs with 50 percent of the work RVU, and we believe this provides a reasonable basis on which to

allocate the indirect PE for services furnished in the facility, including those that have postoperative visits that occur in the non-facility setting. We also note that we retain interest in developing improved approaches to valuing and paying for care furnished during global surgery periods, and we are particularly interested in how to best address the lack of site of service differential for post-operative visits under the current construct.

Comment: Some commenters stated that the proposed reductions threaten medical education infrastructure critical to addressing physician shortages. The commenters indicated that many primary care residencies, physician assistant programs, nursing education programs, and behavioral health training sites operate in facility-affiliated clinics and depend on current payment structures for financial viability. The commenters expressed concern that given existing primary care and behavioral health workforce shortages, the policy could lead to program closures, reduced training capacity, and fewer healthcare providers serving Medicare beneficiaries.

Response: We appreciate the concerns from commenters regarding health care infrastructure costs. As a general matter, we believe that the PE RVUs under the PFS are required to reflect the costs incurred by physician and professional practices, not by larger institutions.

Comment: Several commenters recommended CMS consider exemptions for particular services, such as for:

- Services provided by training programs, to preserve the educational mission while still achieving the policy's intended goals.
- Specific behavioral health codes, which are critical for developmental, neuropsychological, and chronic illness management.
- Rural physicians who split time between office and facility settings.
- Retinal specialists requested an exception given that 76 percent of retinal specialists are in private practice.
- Hospital inpatient and observation services (CPT codes 99221-99239) and nursing facility E/M services (CPT codes 99304-99316). Commenters specifically noted the unexpected payment differential between E/M services provided to patients in skilled nursing facility (which is a facility setting under the PFS) versus nursing facility (which is a nonfacility setting under the PFS) stays.

Response: We acknowledge the comments requesting exemptions for specific services or providers. While we have reviewed these requests, we are not persuaded that there are exceptions to be implemented that are consistent with the assignment of PE RVUs that reflect the relative resources involved in furnishing the services. However, we are interested in objective data that would help us understand and improve how indirect PE is allocated across settings of care, both in general and for specific kinds of services. We would consider such information in future rulemaking.

Comment: A commenter supported our proposal as a broad-based improvement but also suggested that we work toward a more precise process for adjusting valuations and payments over time. Some commenters suggested policy alternatives, such as:

- Utilizing targeted adjustments, such as a facility-based physician modifier or separate reimbursement formulas for independent physicians.
- Eliminating indirect PE allocations for facility-based ZZZ add-on codes, as these services would not require any additional practice expense allocation beyond what is already captured in the base procedure codes.
- Establishing minimum indirect allocation thresholds for codes, with requirements for detailed justification when amounts exceed these minimums.
- Considering the specific characteristics of different procedure types, the actual resource utilization patterns, and the varying practice arrangements under which these services are provided. This could include developing separate allocation methodologies for different categories of services, implementing minimum thresholds below which indirect PE allocation would not apply, or creating specialty-specific adjustments that better reflect the actual cost structures within different medical disciplines.

Response: We appreciate the commenters' suggestions for policy alternatives and are particularly interested in interested parties' input regarding a facility-based physician modifier. We note that this proposal supports our goals toward site neutrality and that we will continue to consider other approaches that would further those goals. As such, we may consider these suggestions in future rulemaking.

Comment: A commenter recommended that services billed with the 26 modifier should be exempt from the proposed reduction, as these services incur similar indirect costs across both facility and non-facility settings.

Response: At this time, services billed with the 26 modifier are not impacted by the proposed change in the allocation of indirect PE in the facility setting Our longstanding approach has been to value services billed with the 26 modifier the same in the facility and nonfacility setting, and we did not propose a change to this aspect of our methodology... We could consider how this change might apply to them in future rulemaking.

Comment: Several commenters recommended that CMS not apply the proposed policy to codes with MMM global periods to avoid negatively impacting access to maternity care services.

Response: We agree with commenters that, for the reasons indicated in the CY 2026 PFS proposed rule (90 FR 32593), the indirect PE reduction should not apply to codes with MMM global periods, and therefore, we are finalizing excluding codes with MMM global periods from this adjustment.

Comment: Some commenters stated that this proposal would create substantial financial disruption across multiple medical specialties. The commenters indicated that these impacts extend beyond individual physician income to broader healthcare system effects, including financial harm to independent physicians while simultaneously promoting higher-cost, hospital-based service utilization across the United States healthcare system. The commenters stated that this proposal would create a perverse incentive structure that contradicts CMS' stated goals of supporting independent practice and controlling healthcare costs. The commenters suggested that the policy risks accelerating physician employment by hospitals and health systems, leading to increased utilization of hospital-based services that carry higher facility fees and overall costs to the Medicare program. Other commenters stated that the proposal supports small, independent practices and mitigates hospital-driven cost escalation.

Response: We agree with the commenters who stated that the proposal would be expected to mitigate hospital-driven cost escalation, and that this proposal will incentivize utilization in the most appropriate setting. Reducing overvaluation of physician services furnished in the facility would be expected to reduce incentives to furnish these services in the facility setting due to the higher payment in that setting. Similarly, the increased valuation for services furnished in the nonfacility setting would be

expected to enable independent practitioners to maintain their practices, rather than to facilitate the acceleration of physician employment as the commenter suggests. We note that the payment rates to hospitals under the OPPS are outside the scope of PFS rulemaking and are not impacted by this proposal. We will continue to explore site neutral payment policies in future rulemaking. We appreciate commenters' perspectives regarding the complexity of financial relationships between hospitals and physician practices and, for those reasons among others, intend to continue to consider appropriate refinements in future rulemaking. However, we believe finalizing this policy represents a significant improvement in the accuracy of payment for physician services furnished in the facility setting overall.

Comment: Several commenters stated that the proposal fails to account for the reality that many procedures cannot be safely performed in office settings and that patient safety considerations, rather than financial incentives, should drive site-of-service decisions. Commenters stated that as currently written, the rule could significantly reduce payments for services performed in Ambulatory Surgery Centers (ASCs), most of which are owned and operated by independent physicians and often function as extensions of physicians' offices.

Response: We agree with the commenters that patient safety considerations, rather than financial incentives resulting from inaccurate valuation, should drive site-of-service decisions. We believe that this proposal will avoid incentivizing site-of-service decisions based solely on financial incentives. The statements regarding ASC ownership by physicians support our understanding that there are duplicative payments being made to the same entity for many services furnished in the facility setting.

Comment: Several commenters emphasized that the main driver of site-of-service payment differentials has been the lack of inflationary updates to physician payment, unlike facility payment schedules. Multiple commenters noted that hospitals receive routine market basket updates while Medicare PFS updates have been far below inflation, making this a structural problem that PE methodology changes alone cannot resolve.

Response: We appreciate these comments and acknowledge that differential payment updates can play a significant role in evolving disparities in payment across settings of care. This proposal is not intended to address those disparities in whole. Instead, this policy would help offset the portion of the

payment disparity that is driven by outdated and inaccurate assumptions that drive the way indirect PE RVUs are allocated by setting of care.

After consideration of the comments we received, we are finalizing our proposal to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs beginning in CY 2026.

d. Use of OPPS data for PFS ratesetting

For several kinds of PFS services, we proposed to deviate from the use of the AMA survey data, and instead utilize data from auditable, routinely updated hospital data to set either relative or absolute rates, especially for technical services paid under the PFS. This approach promotes price transparency across settings, offers more predictable ratesetting outcomes, and limits the influence of anecdotal/survey data. We refer readers to sections II.E.24 and II.E.30 of the proposed rule for specific proposals related to radiation treatment delivery and superficial radiation therapy services and remote patient monitoring and remote therapeutic monitoring services respectively and section II.K. of the final rule for specific skin substitutes. Although we proposed different methodologies for use of OPPS data based on service type, we solicited comments on whether it would be preferable to adopt a single methodology, such as a scaler and how such a methodology would account for differences in practice expenses between services, such as services with extensive clinical staff time versus services where the valuation is primarily driven by the equipment costs.

We appreciate commenters' feedback on the use of OPPS data for PFS ratesetting and refer readers to sections II.E.25 and II.E.32 of this final rule for comment summaries and responses related to the proposals for radiation treatment delivery and superficial radiation therapy services and remote monitoring services respectively, and section II.K. of this final rule for comment summaries and responses related to the proposals for skin substitutes.

6. Payment for Services in Urgent Care Centers

In the CY 2025 PFS proposed rule (89 FR 61746 through 61747), we sought comment on urgent care centers, noting that interested parties describe that hospital emergency departments are often used by beneficiaries to address non-emergent urgent care needs that could be appropriately served in less acute settings, but where other settings, such as physician offices, urgent care centers or other clinics, are not

available or readily accessible. Patients enter EDs to treat common conditions like allergic reactions, lacerations, sprains and fractures, common respiratory illnesses (for example, flu or RSV), and bacterial infections (for example, strep throat, urinary tract infections or foodborne illness). Conditions like these often can be treated in less acute settings. We stated that we were interested in system capacity and workforce issues broadly and are interested in hearing more on those issues, including how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments.

In response to our CY 2025 PFS proposed rule (89 FR 61746 through 61747) question about whether the current "Urgent Care Facility" Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings other than the existing place of service codes,, commenters stated that the current place of service (POS) definitions are inadequately differentiated, especially if CMS wishes to encourage proliferation of the type of urgent care centers that can provide suitable alternatives to EDs, noting that POS 11 generally refers to physician offices that provide diagnostic and therapeutic care in an office setting, by appointment, typically during regular business hours; POS 17 generally refers to clinics that are attached to retail operations, such as pharmacies, grocery stores or big box stores, and provide low-acuity primary and preventive health care, such as vaccinations; and POS 20 refers to Urgent Care Facilities but does not adequately differentiate between those that offer services more akin to the typical general practitioner's office and those that offer enhanced diagnostic and therapeutic services and extended hours. They recommended that the creation of a new POS code describing "enhanced'" urgent care centers that offer specific diagnostic and therapeutic services and that operate outside typical business hours could fill this need. In response to our CY 2025 PFS proposed rule (89 FR 61746 through 61747) question about whether the current "Urgent Care Facility" Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings other than the existing code set and valuation, they stated that Medicare's fee-for-service payment systems do not recognize and adequately value services furnished in Urgent Care Clinics (UCCs) and stated that while there is some overlap in the types of professional services furnished in UCCs and physician offices, UCCs that operate for extended hours and that have enhanced diagnostic and therapeutic capabilities incur additional costs to provide these services.

In recent months, an interested party has requested that for CY 2026, we consider adopting a new Place of Service code for "enhanced" urgent care centers as well as create a new add-on G-code to describe the resource costs involved when practitioners furnish certain services in enhanced urgent care centers that offer extended hours and certain diagnostic and therapeutic services. The interested party suggested the following descriptor: *"Visit complexity inherent to evaluation and management associated with medical care services that serve as the immediate focal point for all needed urgent, non-emergent health care services and/or with urgent, non-emergent medical care services that are related to diagnosis and treatment of an unscheduled, ambulatory patient's urgent, non-emergent conditions. (Add-on code, list separately in addition to office/outpatient evaluation and management visits, new or established)"* and recommended that it be valued based on a crosswalk to HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)* and made billable with all levels of office/outpatient E/M visits for both new and established patients when services are furnished in an enhanced urgent care center.

We sought comments from the public regarding whether separate coding and payment is needed for evaluation and management visits furnished at urgent care centers, including whether or not an add-on code would be appropriate or if a new set of visit codes would be more practical. We note that the process for requesting new place of service codes or modification of existing place of service codes is described on the CMS website at *https://www.cms.gov/medicare/coding-billing/place-of-service-codes/process-requesting-new-codes-modification-existing-codes*. Additionally, as discussed in section II.B. of the proposed rule, many PFS services have a site of service payment differential between the facility and non-facility settings under the PFS. Services furnished in the non-facility setting, such as a physician's office, include direct costs for supplies, clinical staff, and equipment, the physician work RVU and indirect practice expense allocated based on the direct costs and the physician work RVU. In the facility setting, the payment rate includes physician work, and the indirect practice expense allocated based on physician work. The direct costs in the facility setting are paid under a different payment system other than the PFS,

such as the OPPS. PE allocated to services furnished in the facility setting is meant to reflect typical costs associated with practice expenses in that setting of care. We note that we proposed a change in our PE RVU methodology to better recognize variations in indirect costs between facility and non-facility settings of care in section II.B. of the proposed rule. We note here that we are likewise interested in understanding how practice costs, including but not limited to indirect costs, may vary among different non-facility settings of care. We requested feedback regarding how either the code set, or the PE methodology might be improved to better recognize the relative resources involved in furnishing services across these kinds of settings.

We received public comments on this comment solicitation. We appreciate the commenters for their comments. After consideration of public comments, we will take the comments into consideration for possible future rulemaking.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes (PMVC) under the PFS, using the same criteria used to identify PMVC, and to make appropriate adjustments.

As outlined in section II.E. of the proposed rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct practice expense (PE) inputs using other data sources, such as the Veterans Health Administration (VHA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recent available data, we assessed the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties such as from the general medical-related community and the public. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services.

In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*https://www.medpac.gov/document/report-to-the-congress-2006-medicare-payment-policy/*), MedPAC discussed the importance of appropriately valuing physicians' services, stating that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, "When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it." We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases, or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*https://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.

- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using current processes for consideration of

coding changes), which may involve consolidating individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous PMVC as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining PMVC in these areas over the upcoming years. As part of our current process, we identify PMVC for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies PMVC for review. Through our public nomination process for PMVC established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of PMVC as well. Individuals and groups may submit codes for review under the PMVC initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS e-mailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase "Potentially Misvalued Codes" and the CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4-01-26, 7500 Security Blvd, Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled "Attention: Division of Practitioner Services, Potentially Misvalued Codes." Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual PMVC review and 5-Year Review process, we have reviewed over 1,700 PMVC to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of PMVC is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), we built upon the work we began in CY 2009 to review PMVC that have not been reviewed since the

implementation of the PFS (so-called "Harvard-valued codes"[16]). In the CY 2009 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth 5-Year Review of Work RVUs published in a separate notice (76 FR 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of PMVC that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of PMVC that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2026 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058 through 73059), we finalized a process for the public to nominate PMVC. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and interested parties may nominate PMVC for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of PMVC may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.

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[16] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high-cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be PMVC appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a PMVC. The public has the opportunity to comment on these and all other proposed PMVC. In each year's final rule, we finalize our list of PMVC.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for PMVC by February 10th and we display these nominations on our public website (*https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending*), where we include the submitter's name, their associated organization and the submitted studies for full transparency. We sometimes receive submissions for specific PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the PMVC initiative. For CY 2026, we received 12 requests concerning various codes as PMVC. The nominations are as follows:

(1) Maxillofacial Prosthetic Services (CPT codes 21076, 21077, 21079, 21080, 21081, 21082, 21083, 21084, 21085, 21086, 21087)

An interested party nominated CPT codes 21076 (*Impression and custom preparation; surgical obturator prosthesis*), 21077 (*Impression and custom preparation; orbital prosthesis*), 21079 (*Impression*

and custom preparation; interim obturator prosthesis), 21080 (*Impression and custom preparation; definitive obturator prosthesis*), 21081 (*Impression and custom preparation; mandibular resection prosthesis*), 21082 (*Impression and custom preparation; palatal augmentation prosthesis*), 21083 (*Impression and custom preparation; palatal lift prosthesis*), 21084 (*Impression and custom preparation; speech aid prosthesis*), 21085 (*Impression and custom preparation; oral surgical splint*), 21086 (*Impression and custom preparation; auricular prosthesis*), and 21087 (Impression and custom preparation; nasal prosthesis) as potentially misvalued based on what they believe to be missing, outdated, and undervalued practice expense inputs. The nominator stated that these misvalued PE inputs (equipment, supplies, and clinical staff time) result in inadequate payment rates to clinicians who furnish these services, which limits patient access to necessary care. The nominator indicated that the physician work values remain accurate for all of the nominated codes.

According to the nominator, maxillofacial prosthodontists provide specialized rehabilitation care for patients with compromised oral and facial anatomy due to conditions such as cancer, trauma, or congenital defects, addressing both physical and psychological challenges experienced by such patients. Custom prosthetic obturators are medical devices that restore vital oral functions in cancer patients with palatal defects. These implant-retained devices are prescribed based on the location of the defect: maxillary obturators for hard palate issues, pharyngeal obturators for soft palate problems, or a combination for both. The primary purpose of the intraoral prostheses is to enable patients to speak, eat, and swallow more naturally. The nominator stated that these implants can improve patients' quality of life and may eliminate the need for feeding tubes.

The nominator was concerned that CMS payment rates for maxillofacial prosthetic services, which were last reviewed in 1995, are outdated. In particular, the nominator stated that CPT codes 21080 and 21081 have undergone significant changes since the development of their PE values in the mid-1990s. At that time, mandibular reconstruction was rare, and removable prostheses were used to align the jaw. Microvascular reconstruction and virtual surgical planning have since transformed the procedures described by CPT codes 21080 and 21081, allowing precise prosthetic rehabilitation during surgery and improving oral function, speech, and quality of life. The nominator asserted that the PE inputs for CPT codes 21080 and 21081 did not account for these advancements, which did not exist in 1995 when the

codes were valued. Furthermore, they stated that when these maxillofacial prosthetic services were valued in 1995, CMS used inaccurate inputs, which they believe did not account for the appropriate clinical staff time and materials required for prostheses. They stated that changes in clinical staff time, supplies, and equipment require the direct PE inputs to be updated.

The nominator stated that significant technological advancements have also occurred for extraoral prostheses, such as orbital (CPT code 21077), auricular (CPT code 21086), and nasal prostheses (CPT code 21087). For orbital prostheses, hand sculpting and painting remain time-intensive tasks, with limited use of 3D technology. In auricular prostheses, 3D technology has significantly improved the waxing process. For nasal prostheses, preoperative scanning now helps to shape the prosthesis, leading to better cosmetic outcomes. All extraoral prostheses (for example, orbital, auricular, and nasal) now commonly use 3D technology, craniofacial implants, and color-matching devices, which were not standard in the 1990s. The nominator asserted that the practice expense inputs for these codes fail to account for these advancements.

Additionally, the nominator asserts that there are other instances where the nominated codes fail to reflect the significant technological advancements in treatment delivery since 1995. The nominator requested an update to the PE inputs for all of the nominated codes, stating that the dental x-ray (ER071), valued at $128,020.91, has been replaced by various pieces of capital equipment. For example, they listed a "CMS Planmeca CBCT Imaging" system, which costs $163,767.66, and stated that this takes the place of the x-ray unit, highlighting a notable price difference between the x-ray machine and the CT. Furthermore, they provided a lengthy list of additional equipment (for example, 3D printer) that is not accounted for in the PE inputs for all of the nominated codes, underscoring the extensive modernization in service delivery since 1995.

To support their nomination, the nominator included information on what they believe to be more accurate PE inputs, including invoices for supplies and equipment. For items where invoices paid were unavailable, price quotes from a supplier were included. In addition, their appendices included recommendations for deleting and adding supplies, equipment, and clinical staff time. For more information, we refer readers to the submitted nomination, which is posted in the public use files for this

proposed rule available on our public website under PFS Federal Regulation Notices at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

Although the nomination stated that the work RVUs are accurate as currently valued, because these codes have not been reviewed in the last 30 years, we believe it is appropriate to examine both PE and work inputs. Given the technological advancements the nominator described, there may also be resulting changes in the physician work involved in performing these services, and therefore, a comprehensive review of both practice expense and work values would be appropriate. While we proposed not to nominate these codes as potentially misvalued, we requested public comments and recommendations, including those from the RUC, to better understand these codes, particularly regarding typical direct PE inputs and work values.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that the current PE inputs for the maxillofacial prosthodontic codes are outdated and undervalued. They emphasized that the codes have not been reviewed since 1995 and stated that the technology and materials used to fabricate maxillofacial prostheses have changed dramatically in the last 30 years. They stated that many of the supplies and equipment now required are not reflected in the existing PE inputs, leading to undervaluation.

A commenter stated that if CMS declines to adopt their submitted recommendations for direct PE inputs, they request that CMS at least designate the codes as misvalued and refer them to the RUC for a full review of both work and practice expenses. They also noted that maxillofacial prosthodontists currently lack representation on the RUC, which further underscores the need for CMS to step in to ensure proper valuation.

Another commenter supported updating CPT code 21085, which is commonly performed by oral and maxillofacial surgeons in conjunction with orthognathic procedures and endorsed the nominator's PE recommendations, noting that the submission was developed in alignment with the RUC's traditional PE format.

Some commenters further suggested that CMS address the practice expense inputs, since the submission followed the RUC's standard format and provided sufficient detail; however, another

commenter encouraged CMS to engage with specialty interested parties before initiating revisions. Overall, the commenters emphasized that leaving these codes unreviewed for more than 30 years has limited access to life-altering prostheses, and that updated valuation is needed in the near future to restore fair access to care given technological advances.

Response: Upon review of the interested parties' request for CPT codes 21076 to 21087, we identified several concerns with the proposed PE inputs. The proposed clinical staff times, such as patient greeting, room preparation, and instruction review, exceed standard times without explanation. We note high and potentially overlapping clinical staff time requests. Additionally, many of the suggested new supply items may not be typically necessary for all head prosthetic codes. Although commenters removed dental X-rays from the PE inputs, they recommended retaining most previous equipment items, supplies, and times, even with the addition of new supplies and equipment. Overall, these substantial resource additions were submitted without supporting documentation and did not include corresponding adjustments to physician work values, despite the integration of advanced technologies that could impact physician work and time. Furthermore, the absence of input from other relevant medical specialties could undermine the completeness and reliability of these PE recommendations.

Comment: The RUC noted that these services are very low volume—some with fewer than 100 Medicare claims annually—and are offered at only a limited number of centers, making them difficult to survey. However, because they are critically important, the RUC is willing to support valuation and direct PE inputs. They also noted that CMS could rely on the detailed and properly formatted PE data already submitted by the commenter.

Response: We appreciate the RUC for its feedback.

After consideration of the public comments and our concerns associated with the practice expense inputs, we are finalizing our proposal not to nominate these codes as potentially misvalued. We reiterate that the RUC expressed willingness to review the valuation and direct PE inputs for maxillofacial prosthetic services and we look forward to reviewing their recommendations in the future.

(2) Supervision of preparation and provision of antigens for allergen immunotherapy (CPT codes 95145, 95146, 95147, 95148, 95149).

An interested party nominated the professional supervision of preparation and provision of stinging insect venom for allergen immunotherapy described by CPT codes 95145 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom*), 95146 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms*), 95147 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms*), 95148 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms*), and 95149 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms*) as potentially misvalued, stating that the current payment rates for these CPT codes do not accurately reflect the practice expenses required for these procedures. The nominator indicated that the cost to manufacture venom therapy has drastically increased since the last time these codes were reviewed by the RUC in 2001, citing higher labor and raw material costs.

Venom immunotherapy, used for treating insect stings, involves extracting venom from various stinging insects like honeybees and wasps. According to the nominator, the manufacturing process is labor-intensive, requiring 520 staff hours to manually extract venom from 130,000 insects per batch, along with substantial equipment investment. The final product is packaged in single, five, or twelve-dose vials for medical use. For more information, we refer readers to the submitted nomination, which is posted in the public use files for the proposed rule available on our public website under PFS Federal Regulation Notices at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

The nominator stated that before 1995, venom products were paid under product-specific HCPCS J-codes, but due to infrequent use and limited budget impact on the Medicare trust funds, CMS retired the J-codes and instead bundled venom products within CPT codes 95145, 95146, 95147, 95148, and 95149. According to the nominator, the current payment rates for these codes are based on the Harvard valuation and have not been surveyed by the RUC since February 2001. The nominator stated that when surveyed in 2001, the PE inputs for these codes only accounted for swab-pad, antigen, syringe, and gloves. In

contrast, the nominator indicated that CPT code 95165 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)*, which was more recently reviewed in 2016 and shares similar PE inputs as the nominated codes, includes additional items such as a surgical cap, gown, mask, alcohol, paper towel, and vial transport envelope. The nominator stated that, according to the 2019 standards for allergen extract compounding under USP Chapter 797,[17] the procedures described by CPT codes 95145, 95146, 95147, 95148, and 95149 require additional supplies and practice expenses, such as sterile powder-free gloves, face mask, hair net/beard net, gown/sterile garb, isopropyl alcohol, paper towel, sterile empty vials, and albumin saline, in addition to the allergenic extract. The nominator stated that these standards also mandate significantly more annual training for providers, including competency observation, media fill test, gloved fingertip test, and corrective actions. Furthermore, the nominator asserted that the overall cost of venom therapy has increased substantially and submitted invoices to support this statement.

At that time, we did not propose the CPT codes submitted by the nominator as potentially misvalued. CPT codes 95145 to 95149 are typically billed in conjunction with CPT codes 95115 and 95117. We noted that the nominator has listed PE inputs that are also included in the inputs for CPT codes 95115 and 95117 and these same inputs may overlap with inputs included in CPT codes 95145 to 95149. While the PE inputs that overlap between CPT codes 95145 to 95149 and 95115 and 95117 may contain the necessary elements, we sought feedback regarding these overlapping PE inputs in relation to billing frequencies and the possibility of duplicative payment. Specifically, we requested comments on whether these inputs overlap and what potential adjustments should be made to avoid duplicative payment. We requested comments regarding the standard minutes for clinical activity code CA008 (Perform regulatory mandated quality assurance activity (pre-service)) and the standard unit measurement for supply code SH004 (albumin saline). Additionally, we sought input regarding the establishment of clinical activity codes for two specific procedures requested by the nominator: cleaning and disinfecting the compounding area, and sterile preparation of compounds.

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[17] https://college.acaai.org/wp-content/uploads/2021/01/Section-21-USP-Compounding-Allergenic-Extracts.pdf.

Furthermore, anomalies were identified related to the clinical activities described by CA021 (Perform procedure/service—NOT directly related to physician work time). Specifically, the typical times associated with these activities in the RUC database are as follows: 2.3 minutes for CPT code 95145, 3.3 minutes for CPT code 95146, 2.3 minutes for CPT code 95147, 3.3 minutes for CPT code 95148, and 4.3 minutes for CPT code 95149. The nominator has requested 10 minutes for all of the nominated CPT codes without providing any justification for this time. Regarding the clinical labor direct inputs (L037D), we sought comments on several aspects of dosage preparation, including but not limited to: the typical number of dosages, the time required for preparation, the number of vials or dosages that can be prepared from each vial, and the total time needed for preparation of these vials and dosages. Additionally, we sought information about the derivation of the 2.3-minute time. This information would help inform the appropriate time for both clinical labor activities.

We received several invoices for mixed and single venom prices from the nominator; however, we are unable to determine the number of individual venoms in the mixed venom preparations. Specifically, supply codes SH009 (antigen, venom) and SH010 (antigen, venom, tri-vespid) are currently priced at $35.58 and $69.21 respectively, with prices last updated in the CY 2024 PFS final rule (88 FR 78967). The nominator stated that the venom cost has increased to $481.50 for a 5-dose wasp venom as of April 1, 2024, and submitted invoices to support this claim to update the current price. Since we are unsure whether these invoices are for mixed or single venom prices, we requested additional invoices and comments regarding the methodology for calculating venom prices using mixture invoices. We requested feedback to gain a broader understanding of these codes, including how standards of practice have evolved over time, as this information can help identify related coding issues.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with CMS that CPT codes 95145 to 95149, which were last reviewed by the RUC in 2001, should be reassessed to accurately reflect physician work and practice expenses. They emphasized the need to update the PE inputs to align with current USP 797 sterile compounding standards and avoid overlap with injection codes 95115 and 95117. Commenters stated that payment for compounding services (CPT codes 95145 to 95149) should remain separate from injection

services (CPT codes 95115 and 95117) because compounding occurs before or after injection visits, while injection codes capture injection-room resources and observation only. According to commenters, these are distinct clinical activities that often occur on different days, demonstrating that the payments for compounding activities and injection services are not duplicative.

Commenters identified specific new tasks per compounding session required under USP 797 section 21, including routine cleaning and disinfection, hand hygiene and garbing, daily temperature logging, and periodic environmental cleaning, and recommended adding new clinical activity codes to reflect these requirements. They proposed specific time allocations for these activities, such as 2 to 5 minutes for cleaning, 5 to 8 minutes for garbing and hygiene, and 15 minutes per surface category for periodic environmental cleaning, amortized per surface category.

Regarding clinical activity times and supervision, commenters provided CMS with information that a typical sterile compounding session for new-patient venom build requires approximately 46 minutes of direct activity, extending to up to 86 minutes when periodic tasks are included, with about 20 minutes involving physician supervision during pre-service review and sterile preparation. They recommended scaling assumptions to add an extra 2 or 3 minutes per vial beyond the standard three-vial setup to account for the additional complexity of multi-vial builds.

Overall, commenters recommended that CMS refine the PE inputs for the codes describing compounding services to reflect USP 797 and avoid overlap with injection services. Since the direct PE inputs have not been reviewed in over 20 years, commenters recommended updating the PE inputs and clinical activity codes to capture USP-required cleaning/disinfection, garbing, temperature logging, and periodic environmental cleaning. Commenters also recommended establishing scalable time assumptions tied to vial counts and dose complexity and further recognizing 20 supervised minutes per routine compounding session.

Response: We appreciate commenters for their feedback and the information submitted.

After consideration of public comments, we have concerns regarding the specific requests made by commenters. Regarding clinical activity time, we received multiple data sources such as USP 797 standards, commenters' requested additions, and RUC standard times.

We are also unsure as to whether USP standards are required in physician offices. Furthermore,

because billing is done on a per-test basis and multiple tests may typically be performed at the same time, we are unclear on the typical times associated with the USP 797 standards per code (as opposed to per batch). At present, we do not have sufficient information to translate the commenters' recommendations into direct PE inputs, and welcome additional information on the typical number of tests performed for these procedures.

We invited the original nominator or other interested parties to resubmit their nomination with information providing additional clarity for consideration in future rulemaking. Therefore, for CY 2026, we are finalizing our proposal not to nominate these codes as potentially misvalued.

(3) Electronic Analysis of Implanted Neurostimulator Pulse Generator/Transmitter (CPT codes 95970, 95976, 95977).

CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*), 95976 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional)* were nominated as potentially misvalued for two reasons identified by the nominator: there has been a significant shift in the clinical specialties utilizing these codes, and the

PE inputs currently assigned to these codes may not accurately reflect the costs associated with analyzing and programming the hypoglossal nerve stimulation (HGNS) system.

The nominator stated that, from 2017 to 2023, there has been a significant change in the clinical specialties that utilize these codes in the non-facility setting. According to the nominator, while CPT codes 95970, 95976, and 95977 were primarily billed by neurologists when last surveyed by the RUC in 2017, the usage of these codes has shifted away from neurologists toward sleep specialists. The nominator asserted that this shift necessitates changes to the work RVUs and PE inputs for these codes. In addition, the nominator stated that many sleep specialists believe CPT codes 95970, 95976, and 95977 do not appropriately reflect the practice expenses involved in furnishing these services. According to the nominator, a survey conducted among several high-volume sleep specialists (the details of which the nominator did not share with CMS) showed unanimous agreement that these codes do not accurately reflect the practice expense inputs. These three codes currently have 0 minutes of clinical staff time included in the direct PE inputs. However, the nominator stated that based on the survey results the typical clinical staff time spent for patient care was 35 minutes for CPT code 95970, 37 minutes for CPT code 95976, and 46 minutes for CPT code 95977. The nominator stated that CPT codes 95970, 95976, and 95977 should reflect the same clinical staff time as similar analysis and programming procedures, such as CPT codes 93150 (*Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming*), 93151 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*), and 93153 (*Interrogation without programming of implanted phrenic nerve stimulator system*). The nominator stated that these codes more accurately account for the clinical staff time.

We stated that we appreciated the nominator sharing their survey results from high-volume sleep specialists, which may indicate potential inaccuracies in the direct PE inputs for CPT codes 95970, 95976, and 95977. However, our review of the submitted information reveals a lack of survey details (for example, sampling methods, data collection procedures), so it is difficult to understand the context of the information provided by the nominator and identify potential biases of this survey. While we acknowledge potential changes in the specialties utilizing these codes, and sleep medicine's Medicare specialty percentage has grown over time, neurology remains the dominant billing practitioner type. For

these reasons, we proposed not to consider these codes as potentially misvalued. We did, however, seek comments and additional information on the information provided by the nominator. This includes any analysis or studies demonstrating that one or more of these codes meet the criteria listed in section II.C.3. of the proposed rule, under "Identification and Review of Potential Misvalued Services," particularly regarding changes in practice expense inputs for service delivery.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters highlighted that CMS correctly observed that neurologists remain the dominant billing practitioners for these codes, despite the nominator's claims. They noted that while sleep medicine physicians frequently manage patient selection, diagnostic evaluation, and longitudinal care, the initial technical electronic analysis of the device is not generally performed by the sleep medicine physician. They thanked CMS for not designating the codes as potentially misvalued based on incomplete evidence and reiterated that the RUC process remains the appropriate and transparent way to evaluate whether services are misvalued and update PE inputs accordingly.

Commenters supported ensuring that the PE inputs reflect current medical practice but stressed that any changes must be based on a transparent and rigorous survey process. They stated that the data submitted by the nominator was incomplete and recommended that CMS request and review detailed survey data referenced by the nominator to assess whether the codes appropriately reflect the intensity, expertise, and time and engage multiple specialty societies in future deliberations to ensure code valuations reflect clinical practice realities.

Response: After consideration of public comments, we do not believe CPT codes 95970, 95976, and 95977 are potentially misvalued. We believe that the current valuation of PE inputs is still appropriate and that neurologists remain the dominant billing practitioner type; therefore, for CY 2026, we are finalizing our proposal not to designate these codes as potentially misvalued. However, we appreciate the comments and encourage interested parties to submit information, such as detailed survey data, for consideration in future rulemaking to ensure accurate valuation.

(4) Excimer Laser Treatment for Psoriasis (CPT codes 96920, 96921, 96922)

An interested party nominated CPT codes 96920 (*Excimer laser treatment for psoriasis; total area less than 250 sq cm*), 96921 (*Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm*), and 96922 (*Excimer laser treatment for psoriasis; over 500 sq cm*) as potentially misvalued, due to the CPT Editorial Panel's recent modifications to the code descriptor and allegedly inaccurate data used by CMS in valuing these services.

According to the nominator, the misvaluation of these codes creates a significant healthcare access barrier by reducing payment for excimer laser therapy, which disproportionately impacts vulnerable populations while potentially increasing overall healthcare costs. The nominator stated that the low payment rates for these codes make it financially unfeasible for dermatologists to offer this FDA-approved treatment, effectively making it unavailable to Medicare beneficiaries despite its proven effectiveness and potential cost savings.

We discussed our review of these codes and our rationale for finalizing the current work RVUs and direct PE extensively in the CY 2025 PFS final rule (89 FR 97797 through 97801). We stated that we disagreed with the RUC recommended work RVUs for CPT codes 96920, 96921, and 96922 of 1.00, 1.07, and 1.32. The RUC noted that there have been multiple reviews of these CPT codes, and the valuation of the codes is currently based on the original valuation over two decades ago in 2002 where the physician time values were lower than the current times. A subsequent review in 2012 adopted new survey times while maintaining the work RVUs from 2002 for CPT codes 96920 and 96922. The RUC noted that for both CPT code 96921 and 96922, with the largest treatment area, the total times had not changed since first implemented more than 20 years ago. At the time we also believed that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure had increased, significant decreases in time should be reflected in decreases to work RVUs. We noted that our proposed work RVU of 0.83 maintained the intensity associated with the 2002 review of CPT code 96920, which we believed to be more appropriate than the significant increase in intensity that results from the RUC-recommended work RVU of 1.00 which nearly doubled the current intensity of the code (89 FR 97797). We had no evidence to indicate that the intensity of CPT code 96920 had increased to this degree given how the surveyed work time had substantially decreased.

For CY 2026, the nominator raised two issues related to these codes. First, according to the nominator, a coding change by the CPT Editorial Panel that was released in 2024 and effective January 1, 2025, modified the code descriptor from "Laser treatment for inflammatory skin disease(psoriasis)" to "Excimer laser treatment for psoriasis." We remind readers that, in April 2022, the RUC referred CPT codes 96920, 96921, and 96922 to the CPT Editorial Panel to capture expanded indications beyond what was currently noted in the codes' descriptions to include laser treatment for other inflammatory skin disorders such as vitiligo, atopic dermatitis, and alopecia areata, and those expanded indications could reflect changes in physician work as compared to the codes' current descriptors. The coding change application was subsequently withdrawn from the September 2022 CPT Editorial Panel meeting when it was determined that existing literature was insufficient and did not support expanded indications at that time. Therefore, these CPT codes were re-surveyed and reviewed at the April 2023 RUC meeting without any revisions to their code descriptors. We note that, according to the CPT Editorial Panel and the RUC's publicly available meeting notes, since the descriptors for CPT codes 96920, 96921, and 96922 were established in 2002, psoriasis is the only approved indication and use for this treatment modality.[18]

While the nominator is working with the CPT Editorial Panel again to expand the indications for excimer laser treatment beyond psoriasis to include other inflammatory skin conditions, they stated that they believe establishing a temporary G- code for interim coverage is necessary and therefore requested that CMS create coding to more accurately reflect the clinically appropriate use of the excimer laser. The nominator states that this would ensure patients with skin conditions other than psoriasis can access excimer laser treatments without delay.

To provide more evidence as to the accuracy of including non-psoriasis inflammatory skin diseases in the code definition, the nominator provided a data compendium supporting the excimer laser's versatility and key studies demonstrating positive outcomes for conditions like vitiligo, atopic dermatitis, leukoderma, and alopecia areata. Reviewing these submitted studies, the nominator stated that sufficient clinical evidence exists to support expanding coverage for excimer laser treatment beyond just psoriasis. The nominator requested that CMS create additional coding to describe the expanded indications for the excimer laser treatment, because the nominator believes that the standard CPT process is time-consuming

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[18] https://www.ama-assn.org/system/files/ap-2023-ruc-meeting-minutes.pdf.

and could leave many patients without adequate care in the interim; thus, implementing a temporary G-code would ensure continued access to this essential therapy for these patients.

Second, the nominator provided additional invoices and data detailing PE costs related to the excimer laser devices. The nominator claimed that their own analysis relies on real-world data (which was not shared with CMS) and shows that CMS has overestimated the utilization rate of excimer lasers. Using their own survey, they found that on average, dermatologists perform 244 excimer laser treatments per device annually, with each treatment requiring approximately 38 to 46 minutes of excimer laser use. This amounts to nearly 15,000 minutes of total utilization per year, resulting in an effective utilization rate of 10 percent, rather than the 50 percent rate currently used by CMS. As stated in section II.B. of the proposed rule, we currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Based on their real-world device utilization data, the nominator calculated the direct PE cost using CMS' standard equipment formula. The calculated equipment costs are $99.88 for CPT code 96920, $105.14 for CPT code 96921, and $120.91 for CPT code 96922. The nominator also stated that CMS currently assumes a maintenance cost of $7,560 for excimer lasers, based on a 5 percent maintenance rate applied to a purchase price of $151,200. However, the nominator stated that excimer lasers are technical devices with substantially higher maintenance costs. According to the nominator, the annual service cost for the excimer laser is $30,000, and they claimed that a laser chamber replacement service costs $44,000; however, as discussed in section II.B. of the proposed rule, we finalized a 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we stated that this estimate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for

determining a different maintenance factor, a variable maintenance factor for equipment cost per minute pricing was not proposed as we did not believe that we had sufficient information at that present time. Therefore, we reminded readers that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs.

Moreover, the nominator asserted that CMS currently does not include the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the direct practice expense cost for these services. Based on our review of the January 2012 RUC recommendations submitted to CMS, it appears that these equipment items were removed by RUC PE Subcommittee for CY 2013. The requestor stated that the gas cylinder (EQ154) costs $6,300 (excluding labor and shipping costs), and the optical delivery system (EQ155) costs $7,429; however, no supporting invoices or evidence of the typicality of the equipment items' usage for these services were provided to support the equipment items' reintegration into the codes' direct practice expense.

Based on this information, the nominator recommended creating a G-code for excimer laser treatment of inflammatory skin diseases. Furthermore, they requested to include their own real-world data on excimer laser utilization rates in the practice expense calculation, adjust the maintenance cost in the practice expense calculation to reflect the actual cost of maintaining excimer laser devices, and reinstate the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the practice expense calculation.

We appreciate the detailed information submitted by the nominator. However, we stated that we continue to disagree that CPT codes 96920, 96921, and 96922 are potentially misvalued. We noted that the CPT code change request was withdrawn from the AMA in September 2022 due to insufficient supporting literature for expanded indications. Additionally, according to RUC's publicly available meeting notes, psoriasis is the only approved indication and use for this treatment modality since the descriptors for CPT codes 96920, 96921, and 96922 were established in 2002. When the codes were resurveyed in April 2023, no descriptor revisions were made, as the available 2021 Medicare claims data indicated that the typical patient was being treated for psoriasis (96920, psoriasis = 79.3 percent).[19]

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[19] https://www.ama-assn.org/system/files/ap-2023-ruc-meeting-minutes.pdf.

Additionally, there have been numerous CPT Editorial Panel applications and actions since the withdrawn application at the September 2022 meeting[20], including a February 2025 action[21]. However, at the time of drafting the proposed rule, the request for expanded indications does not appear to have been re-submitted or revisited by the specialty societies. We sought comments on whether creating a new HCPCS G-code that is not condition-specific would improve payment accuracy for this technology when used to treat conditions other than psoriasis. We also sought information regarding possible barriers to coding changes undertaken through the CPT Editorial Panel process. We sought information regarding the nominator's assertion that equipment items EQ154 and EQ155 are necessary and typical for these services, and invoices to support the nominator's asserted purchase prices, so as to provide a comprehensive understanding of the overall costs associated with these services. We note that, effective for January 1, 2027, based on the publicly available Summary of CPT Editorial Panel Actions from the February 2025 meeting[22], the codes' descriptors will change from "Excimer laser treatment for psoriasis" to "Laser treatment for psoriasis," absent subsequent CPT Editorial Panel actions. Therefore, we believe it is important for comments to support the typicality of these equipment items regardless of the type of laser used for these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters noted the FDA approval of the excimer laser for vitiligo, including its proven safety and effectiveness, and patients' reliance on the laser if they cannot tolerate stronger systemic medicines. At its May 2025 meeting, the CPT Editorial Panel approved revisions to these code descriptors to include inflammatory and autoimmune skin indications beyond psoriasis, with the updates effective January 1, 2027 and the majority of commenters supported the CPT Editorial Panel process and affirmed support for the RUC's valuation of physician services.

Many commenters expressed support for establishing an interim G-code for excimer laser treatment (CPT codes 96920, 96921, 96922) to ensure immediate patient access while permanent CPT code revisions are being developed which would sunset upon implementation of the revised CPT code

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[20] https://www.ama-assn.org/system/files/september-2022-cpt-summary-panel-actions.pdf.
[21] https://www.ama-assn.org/system/files/feb-2025-summary-of-panel-actions.pdf.
[22] https://www.ama-assn.org/system/files/feb-2025-summary-of-panel-actions.pdf.

descriptors. Without a G-code, commenters noted that they are forced to bill under the unlisted CPT code 96999, which creates an administrative burden for prior authorizations and results in inconsistent reimbursement. Other recommendations included reassessing utilization and maintenance inputs to reflect real-world conditions and adding essential equipment items omitted in practice expense calculations. Commenters stated that by making excimer laser therapy financially unsustainable for dermatology practices, CMS is unintentionally pushing patients toward more aggressive and significantly more expensive treatments, such as biologics.

Response: We appreciate the support for the CPT editorial panel's revisions and look forward to reviewing them, and the subsequent RUC recommended values when we receive them for the subsequent years' rulemaking (for CY 2027, this would be by February 10, 2026). Although we recognize that there may be a "gap" in specific coding for these services for the period of time between when the CPT editorial panel completes their revisions and CMS is able to finalize updated valuation, as of the publication of this final rule, the code descriptor changes referenced by the commenters has not been finalized by CPT and creation of a G-code may only cause further confusion.

Regarding valuation of the existing CPT codes, commenters stated that excimer laser therapy typically requires around 15 sessions (depends on patient response to treatment), with a national average (current) reimbursement of $136.83 to $182.76 per treatment, which brings the total cost of excimer laser therapy to $2,000 to $2,750. Other commenters stated that average excimer treatments per site amount to roughly 10 to 30 minutes (6 to 12 treatments x 40 to 45 minutes per treatment) per year. Some commenters recommended CMS adopt the RUC-recommended work RVUs and that the proposed work RVUs (0.83, 0.90, and 1.15 respectively) grossly undervalue the intensity of excimer therapy, which some commenters stated requires 40 to 60 minutes of precise dosing, repositioning, and sparing healthy skin-often in patients with multiple comorbidities. Several commenters stated that the RUC's practice expense values ($80, $83, and $100 respectively) align with the real costs incurred and that CMS' standard assumption of 50 percent utilization is unrealistic.

Other commenters requested that CMS update the PE inputs for the existing CPT codes to reinstate the costs of the consumable gas cylinder (EQ154) and optical delivery system (EQ155) into the direct practice expense (PE) inputs for CPT codes 96920 to 96922. They recommended CMS incorporate

EQ154 and EQ155 into a supply-based reimbursement structure that is applied only when excimer laser systems are used when furnishing these services. A few commenters noted that excimer lasers are gas-based lasers that rely on a mixture of noble gases, including high-purity neon, to generate precise, targeted monochromatic ultraviolet (UVB) light at wavelength of 308 nanometers. This specific wavelength is critically important for the effective treatment of vitiligo, psoriasis, and other dermatological conditions by targeting and suppressing the autoimmune response in affected skin areas without the need for broad-spectrum light therapy.

Response: We appreciate the information provided by commenters regarding the valuation of the existing CPT codes describing these services. As these codes are likely to be reviewed by the RUC, and recommendations provided for future rulemaking, we will not be making any changes to the valuation at this time.

After consideration of public comments, for CY 2026, we are finalizing our proposal not to nominate CPT codes 96920, 92921, and 96922 as potentially misvalued.

(5) Optical Coherence Tomography (OCT) of Retina (CPT code 0605T)

CPT code 0605T (*Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days*) was submitted as potentially misvalued. This code is a temporary CPT category III code and is assigned procedure status "C" (contractor priced) under the PFS. The nominator generally expressed concern that the initial pricing by the contractor was inaccurate and did not appropriately consider the cost of the OCT device when provided by the independent diagnostic testing facility (IDTF). The nominator requested that CMS revise the valuation of this code to properly account for the cost of the OCT imaging device used to provide this remote diagnostic retinal monitoring service.

The nominator stated that remote OCT allows for better management of patients with neovascular age-related macular degeneration (NV-AMD) and improved management has been shown to result in

reduction in treatments.[23,24] According to the nominator, one of the Medicare Administrative Contractors who priced the service did not appropriately consider the cost of the OCT device provided by the IDTF, resulting in an inadequate payment rate that did not cover the direct operating costs. The nominator asserted that this code is misvalued because the contractor established its value by crosswalking to the valuation for remote physiological monitoring (RPM) CPT code 99454 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*). The nominator stated that CPT code 99454 represents a distinct type of service and falls under a different benefit category than remote OCT. The nominator stated that while remote OCT is a diagnostic service that is provided by an IDTF, CPT code 99454 is an E/M service that is not permitted to be furnished by IDTFs. In addition, the device used to furnish remote OCT performs retinal imaging comparable to that performed in the physician office, has a useful life of 5 years, and costs $40,000. The nominator provided an invoice to support this claim. In contrast, the nominator indicated that the device used in the service described by CPT code 99454 captures simple physiologic data and costs $1,000. The nominator provided a device equipment cost per month of $666.67 for the device used to furnish remote OCT. Using the device cost calculation, the nominator estimated an unadjusted rate of $632.22 by following CMS' valuation methodology.

Overall, the nominator stated that CPT code 99454 is not an accurate crosswalk for remote OCT and recommended that CMS revise the valuation of CPT code 0605T to properly account for the higher cost of the OCT imaging device used to provide this remote diagnostic retinal monitoring service. The nominator stated that due to the current undervaluation, the prescribing physicians and their patients in need of remote monitoring of a treatable sight-threatening retinal disease do not have access to this service.

We did not propose CPT code 0605T as a potentially misvalued code. We note that the nominator submitted a single invoice in support of its assertions, which may not be reflective of typical costs, and

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[23] Holekamp, Nancy M., et al. "Prospective trial of Home OCT guided management of treatment experienced nAMD patients." *RETINA* (2022): 10-1097.

[24] Heier, Jeffrey S., et al. "Clinical Use of Home OCT Data to Manage Neovascular Age-Related Macular Degeneration." *Journal of VitreoRetinal Diseases* (2024): 24741264241302858.

we encourage interested parties to provide additional information. including invoices for the OCT devices. Also, we welcomed comments on whether this code should be nationally priced and what inputs should be used if we were to set a national rate for this service.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported establishing a national payment rate for remote OCT technology (CPT code 0605T) that reflects its clinical value and operational costs. The commenters emphasized that while CPT codes exist for remote OCT services, current payment rates are inadequate and payment implementation has lagged, limiting patient access to this innovative technology. Commenters stated that neovascular age-related macular degeneration (nAMD) is highly prevalent in the Medicare population and that remote OCT technology allows retina specialists to monitor patients more frequently while reducing in-person visits by 40 to 50 percent. They noted that this remote OCT enables earlier detection of disease reactivation, timely as-needed treatment, and prevention of irreversible vision loss, thereby preserving patients' vision and quality of life.

Many commenters supported the invoice provided by the nominator indicating a price of $40,000 for the purchase of the remote OCT device and stated that the current rate of $47.77 provided by some MACs was inaccurate. Commenters stated that $40,000 is a reasonable cost for the innovative technology which incorporates high-resolution imaging, AI analysis, and secure data systems. Another commenter stated they submitted an invoice for an OCT system that costs $44,500. Commenters stated that for this technology to be widely available, CMS should recognize its value through an appropriate national price for the technical component 0605T.

Some commenters highlighted that RPM is not the right comparator for OCT. They stated that CPT code 99454 pays for monitoring physiologic metrics like blood pressure or weight and for longitudinal care-management time; they are not diagnostic imaging tests with acquisition, interpretation, and report requirements, which are not comparable to OCT based remote monitoring. They suggested that using a cardiology service is a more likely comparator, for example mobile cardiovascular telemetry (MCT) CPT code 93229 (*technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician*

or other qualified health care professional). CPT code 93229 describes a 30-day diagnostic monitoring episode with remote attended surveillance center analysis and reporting, which commenters suggest would be an operational match to OCT's remote surveillance center model.

Response: We appreciate the feedback from commenters and for highlighting that this innovative remote in-home OCT device can be particularly beneficial for patients with nAMD. We agree that the comparator RPM code, CPT code 99454, may not fully account for the resources and expertise involved, or the OCT devices and/or systems as described by CPT code 0605T and that the current payment is inadequate to reflect the OCT device used to monitor nAMD in patients in the home setting. After consideration of public comments, for CY 2026, we are finalizing national pricing for CPT code 0605T for CY 2026. We agree with commenters that CPT code 93229 has similar resources costs, and therefore, we are establishing inputs for CPT code 0605T using CPT code 93229 as a direct crosswalk for valuation.

(6) Mechanical Separation of Plasma from Blood (CPT code 36514).

An interested party nominated CPT code 36514 (*Therapeutic apheresis; for plasma pheresis*) as potentially misvalued for two PE-related reasons. The first concern involves the assigned clinical labor code, L056A (RN/OCN), which the nominator states undervalues the therapeutic apheresis nurse's operating wage cost. The second concern relates to the equipment code, EQ084 (cell separator system), specifically its price and equipment utilization rate.

The nominator presented differences in therapeutic plasmapheresis or plasma exchange (TPE) procedure payments between settings, with 50 percent to 75 percent of the 100,000 annual TPE procedures occurring in hospital outpatient settings. The nominator stated that the payment differential is substantial: under the Hospital OPPS, the average CY 2025 Medicare payment rate for TPE performed in a hospital outpatient department is $1,639.28, excluding compensation for the supervising physician. In contrast, under the PFS, the average CY 2025 Medicare payment rate for the same procedure performed in a non-facility setting is $663.43. According to the nominator, the differences in payment rates have forced patients to receive treatment in more expensive hospital outpatient settings, as physicians cannot financially sustain the costs of performing TPE services in non-facility settings under the current payment rates. The nominator asserted that this payment structure not only limits patient access to care but also results in higher overall costs to the Medicare program, as procedures are channeled to the more

expensive hospital outpatient setting where payment rates are nearly 2.5 times higher than non-facility rates.

The nominator stated that TPE is a complex extracorporeal blood therapy procedure used to treat patients with serious hematological, oncologic, neurological, rheumatologic, cardiac and autoimmune disorders. Therapeutic apheresis nurses performing this procedure require extensive specialized training to independently handle patients with a wide spectrum of serious illnesses and comorbidities. They must be trained and highly skilled in evaluating patients and managing clinical issues and adverse events that commonly arise during the procedure, particularly in patients with comorbid anemia, renal failure, cardiovascular disease, serum protein abnormalities or other risk factors.[25] Their key responsibilities include advanced vascular access, continuous management of the extracorporeal circuit, troubleshooting, patient assessment to manage adverse events, and medication administration. The nominator emphasized that therapeutic apheresis nurses' training and skill level are distinct from nurses collecting blood products from healthy donors.

The nominator summarized the wide range of median annual and hourly base salaries ($92,525 to nearly $125,000) for "Apheresis Nurse" or "Apheresis RN" positions identified across four leading online employment recruiting firms. According to the nominator, this variability likely stems from the differing mixes of higher-paid therapeutic apheresis nurse job postings versus lower-paid postings for nurses collecting blood products from healthy donors at community blood centers across these firms. Based on the listed position openings, the nominator found that the rate per minute for a therapeutic apheresis nurse, inclusive of benefits, likely ranges between $1.30 and $1.50 per minute, well over 60 percent higher than the $0.81 per minute valuation currently assigned to CPT code 36514 with the L056A labor code. Also, the nominator claimed that to accurately assess therapeutic apheresis nurse wages, other surveys could be employed focusing on nurses performing therapeutic procedures while excluding those working in blood/plasma collection centers from healthy volunteer donors, as the latter typically receive lower compensation despite using similar equipment.

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[25] Chhibber V and King KE. Management of the therapeutic apheresis patient (Chapter 12). In: *Apheresis: Principles and Practice, 3rd Edition*. Bethesda, MD: AABB Press, 2010.

The nominator proposed that CMS collaborate with the Department of Labor to accurately assess therapeutic apheresis nurse salaries and establish a new clinical labor code with appropriate per-minute rates. This would replace the current L056A labor code used for CPT code 36514, which the nominator asserts undervalues these specialized nurses' wages and benefits. The new code would specifically exclude non-patient-facing nurses who perform blood product collection, ensuring more accurate compensation for this specialized role.

According to the nominator, the current Medicare payment rate for CPT code 36514 in the non-facility setting fails to adequately account for direct PE costs. First, based on fourth quarter 2024 U.S. sales data, the nominator requested updating the CMS Equipment File price for the cell separator system equipment code (EQ084) from $81,656.40 to $93,321.35, reflecting current market conditions. According to the nominator, the current rate of 0.5 for equipment code EQ084 implies that facilities perform 426 procedures per year per device; however, data from major hospitals, including the three largest-volume hospitals in the U.S., demonstrates that facilities average only 181 procedures per year per device, suggesting a more accurate utilization rate of 0.21. This discrepancy can significantly impact on the calculated costs and subsequent payment rates for equipment code EQ084.

After reviewing the nominator's submission, we did not believe that we had enough information to evaluate whether CPT code 36514 is potentially misvalued, and thus we did not propose the code as potentially misvalued at this time. To assist us in further considering whether CPT code 36514 is potentially misvalued, we sought information on the direct practice expense inputs, particularly regarding the clinical labor code L056A and equipment code EQ084. Specifically, we sought comments on whether to establish a new therapeutic apheresis nurse clinical labor code in the non-facility setting. Also, we sought invoices and other associated information that could be used to update the cell separator system equipment code EQ084 to reflect current market costs. We do not believe an update to the equipment utilization rate is necessary. We disagreed with the nominator that an equipment utilization rate of 21 percent would be typical for the cell separator system. As we stated previously, we currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act. As we discussed in the CY 2021 PFS final rule, it would distort relativity to

assign a utilization rate of 21 percent for the cell separator system equipment, as this would have the same effect as doubling the overall price of the equipment (85 FR 84629).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS's decision in the CY 2025 final rule to adopt the RUC-recommended direct practice expense inputs for CPT code 36514 (therapeutic apheresis, plasma pheresis), which utilizes the L056A (RN/oncology nurse) clinical labor category, affirming and assuming that the code is appropriately valued. They encouraged CMS to continue reviewing and updating these codes as necessary.

Response: After consideration of public comments, we are finalizing our proposal not to nominate this code as potentially misvalued.

(7) Remote Interrogation Device Evaluation (CPT code 93296)

An interested party nominated CPT code 93296 (*Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*) as potentially misvalued, because the service has experienced substantial changes in PE. The nominator emphasized that the current direct practice expense inputs do not accurately represent either the current standard of care or the actual resources required to provide the service, necessitating an urgent review of the code's resource input valuations.

CPT code 93296 is a technical component-only code describing remote monitoring of cardiac devices over 90 days. The nominator stated that this service enables healthcare providers to remotely evaluate implanted cardiac defibrillators and pacemakers, review device data, communicate with patients, and share findings with physicians. The monitoring helps prevent emergencies and reduces hospitalizations through early intervention and timely device adjustments. According to the nominator, the code's direct costs, last reviewed by RUC in 2016 and implemented in 2018, no longer reflect current service delivery requirements because technological advancements and expanded monitoring protocols have significantly increased service complexity and resource requirements.

Additionally, according to the nominator, the service delivery for CPT code 93296 has evolved significantly, requiring enhanced organizational infrastructure and specialized clinical expertise. They stated that modern service delivery involves complex data management, with each transmission requiring 32 distinct tasks[26] for complete patient care. The increased service complexity stems from advanced technology requirements, expanded patient monitoring needs, and more frequent device interrogation, shifting from quarterly to more regular intervals. These changes have created a notable disparity between current resource costs and existing valuations, necessitating updated mechanisms for data management and prioritization.

According to the nominator, the direct cost inputs for clinical labor and equipment do not reflect the current direct costs required to furnish the services. The nominator stated that the total direct cost of $25.84 (including clinical labor and equipment) exceeds the CY 2025 national non-facility PFS payment rate of $19.41. They stated that the current valuations do not reflect modern clinical staffing needs and equipment requirements for this pacemaker interrogation system service, despite similar updates being approved for comparable diagnostic services. To assess resource requirements, the nominator conducted an independent study among IDTFs, using standardized data collection and a volume-weighted analysis of 2023 service data. The nominator claimed that their findings demonstrate a significant disparity between current valuations and actual service delivery costs, supporting the need for comprehensive input review.

The study of IDTFs conducted by the nominator revealed that CPT code 93296 requires 83.66 minutes of non-physician clinical labor time, significantly more than CMS' current value of 28 minutes. This time encompasses eleven distinct tasks, from patient enrollment to quality assurance, with the most time-intensive activities being data review and analysis (25.25 minutes) and unscheduled alert management (21.84 minutes).

TABLE A-C1: LIST OF NON-PHYSICIAN CLINICAL LABOR TIME FROM THE NOMINATOR'S SURVEY

Description	Time (minutes)
Patient enrollment and verification	0.08

[26] Aileen M. Ferrick et al., 2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Practical Management of the Remote Device Clinic (2023), https://www.hrsonline.org/guidance/clinical-resources/2023-hrsehraaphrslahrs-expert-consensus-statement-practical-management-remote-device-clinic?gad_source=1&gclid=Cj0KCQiAkoe9BhDYARIsAH85cDOusU-vRRcEnwoXzUmN2COkX0_DiRVHuOM8cYMf8riBNXW-KrFagnAaAs5NEALw_wcB.

Description	Time (minutes)
Patient education and consent	0.90
Device preparation and setup	3.20
Data review and analysis	25.25
Unscheduled event and episode evaluation	8.70
Unscheduled alert management and reporting	21.84
Unscheduled transmission data archival and documentation	1.46
Scheduled summary report preparation and delivery	6.17
Patient support and inquiry response	2.96
Manual transmission and connectivity management	3.47
Quality assurance of alert and routine reports	9.63

Furthermore, the nominator stated that while the valuation for CPT code 93296 is currently based on electrodiagnostic technologists (L037A) at $0.44 per minute, the service is typically performed by cardiovascular technicians (L038B), who receive $0.60 per minute. Thus, the nominator believes that updating both the time and clinical staff classification is needed for accurate service valuation and consistency with other implantable device monitoring services.

Finally, the nominator requested two updates to the equipment costs for CPT code 93296. First, they recommended adjusting the equipment usage time to align with the updated clinical labor time for remote interrogation device evaluation. Second, they recommended changing the assigned equipment code from "pacemaker interrogation, system" (EQ320) priced at $123,250 to "pacemaker follow-up system" (EQ198) priced at $279,453. We note that no invoices were submitted to support these prices. The nominator believes that these changes would align the equipment valuation with actual costs and match similar CMS-approved device monitoring services.

Overall, the nominator stated that a review of CPT code 93296 current inputs reveals significant undervaluation in several key areas. According to the nominator, the existing resource costs for clinical labor times, labor types, and equipment costs do not adequately reflect the current service requirements. Based on the submitted information, however, we proposed not to nominate this code as potentially misvalued. We requested that the nominator submit a complete report detailing the associated direct practice expense input assessment data to enable us to more fully consider whether the code is potentially misvalued. Additionally, we requested comments, including any analysis or studies from the broader medical community, including the RUC, regarding whether this service has experienced substantial changes in practice expenses since its last review.

We received public comments on these proposals. The following is a summary of the comments

we received and our responses.

Comment: Numerous commenters suggested that CMS re-evaluate and accurately value CPT code 93296, noting that the current valuation significantly understates the time, skill, and resources needed to provide remote monitoring of pacemakers and implantable cardioverter defibrillators (ICDs). Commenters stated that the CMS assumption of an electrodiagnostic technologist (L037A) spending 28 minutes to complete a full 90-day monitoring cycle does not reflect reality. Commenters provided a number of recommendations regarding the time associated with the electrodiagnostic technologist completing the full 90-day monitoring cycle. The most commonly reported time was over 80 minutes, while some commenters reported a range of 10 to 30 minutes. A few commenters stated that clinicians may spend a minimum of 10 minutes or up to 100 minutes per patient over a 90-day cycle, performing tasks such as data review, triage of alerts, patient communication, documentation, and integration with the electronic medical record.

Commenters also stated that these evaluations cannot be effectively performed by electrodiagnostic technicians (L037A) alone but instead require skilled professionals, at minimum certified cardiovascular technicians (L038B), due to the complexity of interpreting cardiac rhythms and device functionality with high levels of quality and accuracy. They highlighted that this distinction impacts both labor costs and the quality of care, as specialized expertise is necessary to ensure timely intervention, prevent hospitalizations, and optimize patient outcomes.

Commenters also stated that technology has evolved beyond the basic transmitters assumed in the original valuation. According to the commenters, pacemaker and ICD monitoring today requires the same integrated hardware-and-software platforms used for implantable loop recorders, systems capable of continuous data acquisition, algorithmic event detection, alert management, and secure data sharing, but the current equipment code (EQ320; pacemaker interrogation, system) does not reflect this infrastructure. Some commenters stated that they use a universal remote monitoring software, such as MURJ, EPIC, and Medtronic CareLink, and noted that there is no functional difference in the tools or infrastructure required for these services.

Overall, commenters suggested that CMS revise the valuation for CPT code 93296 to more accurately reflect the actual time, technician level, and tools required. They suggest CMS work with

professional societies to adopt valuations that better reflect the scope of care and modern standards of practice and immediately update the PE inputs for CPT code 93296 or refer the code to the RUC for full review.

Response: After considering public comments, we found significant variation in the evaluation time estimates submitted by commenters, ranging from 10 to 100 minutes per patient for a comprehensive 90-day remote evaluation of a pacemaker or implantable cardioverter-defibrillator (ICD), making it difficult to identify a typical evaluation time. We welcome additional feedback from interested parties on the typical times associated with this clinical labor activity.

Based on the supporting evidence, we agree with commenters that the technician for this code should be a cardiovascular technician (L038B) rather than an electrodiagnostic technician (L037A). In addition, we agree that the current equipment code EQ320 should be updated to EQ198, as suggested, and therefore, we are making these updates for CY 2026.

Comment: The RUC stated that it reviewed the direct PE inputs for these services in January 2018. Since the RUC did not receive any interest from the specialties that perform this service to review it again, it has no plans to reassess CPT code 93296 or provide further commentary on it at this time.

Response: We appreciate the RUC for their feedback.

Based on our review of public comments we are finalizing our proposal not to nominate these services as potentially misvalued. However, we are finalizing updates to the clinical labor types and equipment types as described previously.

(8) Fine Needle Aspiration (FNA) (CPT codes 10021, 10004, 10005, 10006)

An interested party requested that CMS reconsider CPT codes 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), 10004 (*Fine needle aspiration biopsy, without imaging guidance; each additional lesion*), 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) for nomination as potentially misvalued, citing significant undervaluation since 2019. The nominator submitted a request to CMS for the reevaluation of these codes, stating that the payment changes have created a concerning cascade of negative consequences impacting the care of patients with thyroid nodules and cancer. Specifically, the nominator questions the fundamental basis of CMS' 2019

work RVU reductions for FNA procedures. While the RUC recommended work RVUs of 1.20 for CPT code 10021 and 1.63 for CPT code 10005, CMS instead implemented lower values of 1.03 and 1.46, respectively. The nominator strongly disagreed with CMS' methodology, particularly its comparison to CPT code 36440 (neonatal blood transfusion). The nominator stated that this crosswalk comparison is inappropriate because the neonatal procedure represents a fundamentally different type of service with distinct work intensity levels, requires different expertise, is rarely billed to Medicare, and serves an entirely different patient population than FNA procedures.

The nominator further emphasized that when the work RVU for CPT code 10005 was reduced by 10.5 percent (from 1.94 to 1.46), it triggered a much larger 35.7 percent drop in payment. This substantial decrease has forced a significant shift in where these procedures are performed, moving from office-based settings to hospital facilities. Using claims data, the nominator stated that there has been a shift in the site of service for FNA procedures between 2018 and 2023; the percentage of procedures performed in facility settings increased from 52.06 percent in 2018 to 57.05 percent in 2023. Conversely, services performed in office settings declined from 47.05 percent in 2018 to 42.40 percent in 2023. The nominator claimed that this shift in performance of FNA from the office setting to hospital outpatient departments resulted in Medicare paying 524 percent more for the same procedure. With an additional cost of $584.92 per procedure at facility locations, the nominator claimed that this shift has resulted in increased Medicare expenses of $4.17 million.

Beyond the financial implications, the nominator stated that the low valuation of this code family has resulted in a shift to facility settings raising Medicare costs, reducing access, and reducing quality of care. According to the nominator, most concerning is the long-term impact on medical education, as new endocrinologists and surgeons are now avoiding learning FNA procedures altogether. Furthermore, the nominator referenced a study,[27] which discusses the potentially negative consequences of code devaluation on patient care and healthcare spending. Overall, to address these issues, the nominator specifically requested that CMS restore the work RVU values to those originally recommended by the RUC in 2019, stating that CMS' previous crosswalk to neonatal transfusion described by CPT code 36440

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[27] THYROID Volume 34 Number 11, 2024 *https://doi.org/10.1089/thy.2024.0442* Eldeiry, et al. "Impact of Changes in Fine Needle Aspiration Biopsy Reimbursement on Clinical Care of Patients with Thyroid Nodules in the United States".

(*Push transfusion, blood, 2 years or younger*) was inappropriate given the significant differences in work intensity levels and required expertise between the procedures.

We appreciate the comprehensive information provided by the nominator, including their reference to recent research and detailed trend analysis. However, we note that these codes have undergone multiple recent reviews. Our review of these codes and our rationale for finalizing the current values are extensively discussed in the CY 2019 PFS final rule (83 FR 59517) and CY 2021 PFS final rule (85 FR 84599). Furthermore, this code family was previously nominated two times as potentially misvalued and discussed in the CY 2020 PFS final rule (84 FR 62625) and CY 2025 PFS final rule (89 FR 97743). For more information, we encourage the nominator to reference the discussions in previous rulemaking. We maintained our position and were not proposing this code family as potentially misvalued. We acknowledged the shift in site of service for FNA procedures between 2018 and 2023. We will continue to monitor the site-of-service trends closely. Should these patterns persist or accelerate, a new survey in the future may be necessary to accurately reflect these changes in practice patterns. We requested public comments and recommendations, including those from the RUC, regarding whether these codes should be re-reviewed in light of the information submitted by the nominator.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The RUC stated that it received notification of interest from a specialty society to re-review CPT codes 10005 and 10006. While the RUC indicated that it would place the fine needle aspiration codes (CPT codes 10005 and 10006) on its next Level of Interest (LOI) to review these services and submit recommendations for CY 2027, the RUC strongly suggests CMS to correct the previous error in valuing these services. The RUC reiterated that it has repeatedly commented on a mathematical error by CMS in valuing the fine needle aspiration codes, where CMS double-counted utilization data for codes with bundled image guidance, leading to incorrect assertions about a 20 percent physician work increase. The RUC suggested CMS to correct this computational error and accept its previously recommended work RVU values of 1.63 for CPT code 10005, 2.43 for CPT code 10009, and 1.20 for CPT code 10021. A few commenters stated that the codes are undervalued due to a double-counting error and expressed disapproval of CMS' refinement methodology, emphasizing that

CMS should correct the mathematical error underlying the current work RVUs for CPT codes 10005, 10009, and 10021 and adopt the 2019 RUC-recommended values of 1.63, 2.43, and 1.20, respectively, which would resolve the issue.

Response: We reiterate that our review of these codes and our rationale for finalizing the current values were discussed in the CY 2019 PFS final rule (83 FR 59517 through 59521) and the CY 2021 PFS final rule (85 FR 84602 through 84604). We further explained this issue in the CY 2025 PFS final rule (89 FR 97743 through 97745).

Comment: A few commenters supported our proposal not to nominate the fine needle aspiration code family as potentially misvalued.

Response: We appreciate commenters for this feedback.

We appreciate the RUC placing the fine needle aspiration codes on its next LOI for CY 2026, and we are finalizing our proposal not to nominate these codes as potentially misvalued.

(9) Nasal Sinus Irrigation (CPT codes 31000 and 31002)

An interested party nominated CPT codes 31000 (*Lavage by cannulation; maxillary sinus (antrum puncture or natural ostium)*), and 31002 (*Lavage by cannulation; sphenoid sinus*) as potentially misvalued. The interested party expressed concern that these codes are undervalued due to missing pricing data for essential lavage supplies and stated that they are not currently priced in the non-facility setting.

Regarding both codes, the interested party identified two issues. They stated that this procedure uses the Cyclone® sinonasal suction and irrigation system, and requires additional tools, staff time and supplies. For CPT code 31000, the interested party stated that while the current PE supplies are valued at $33.68, this amount should be $333.68, reflecting a $300 increase to include the Cyclone device cost. Similarly, for CPT code 31002, the interested party proposed increasing the supply price from $26.74 to $326.74 to incorporate the Cyclone device cost. To support this claim, the interested party has provided seven paid invoices demonstrating the actual cost of the system.

The interested party also claimed that both codes do not have non-facility RVUs but are primarily performed in non-facility settings. According to the AMA's RUC database's procedure volume data, CPT

code 31002 is performed in the non-facility setting 81.4 percent of the time and CPT code 31000 is reported 77.2 percent of the time in the non-facility setting.[28]

The interested party emphasized that these misvaluations have real-world implications for patient care. The current valuations may limit physicians' ability to provide these services in both facility and non-facility settings, potentially affecting patient access to care, particularly for those who can only receive treatment in physician offices. Thus, the interested party requested a revaluation of the PE components for both codes and the establishment of non-facility PE inputs for these services.

Although we proposed not to designate these codes as potentially misvalued, we acknowledged the interested party's concerns about their current valuation. Specifically, these concerns could stem from missing pricing data and observed changes in the typical site of service and dominant specialty since the last valuation. We noted that CPT code 31000 is typically performed in the non-facility setting but question whether the Cyclone device is either typically used or necessary for the performance of this procedure. We noted that CPT code 31002 does not have non-facility PE inputs, however it seems to typically be performed in the office setting with the dominant specialty listed as Allergy/Immunology and not Otolaryngology. We also questioned whether the Cyclone device is either typically used or necessary for the performance of this procedure. We believed that both codes would require a comprehensive review to address these potential changes in typical site of service and dominant specialty, as well as PE valuation. We requested public comments regarding these issues concerning CPT codes 31000 and 31002. Interested parties were encouraged to submit relevant documentation, such as invoices or other evidence that demonstrates the typical resource costs for providing these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters, including the RUC, supported our proposal. The RUC stated that they did not receive any interest from allergy/immunology or otolaryngology specialties that perform these services. According to the RUC, the specialties noted that publicly available CMS data suggest a single allergy practice is primarily driving the use of CPT code 31002. If the allergy practice utilization is removed, otolaryngology is still the dominant specialty for this service. Additionally, the specialties agree

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[28] *AMA RBRVS DataManager*. American Medical Association. (2025, January 15). https://www.ama-assn.org/.

with CMS that it is unclear whether the Cyclone product is "typical" for these procedures. Therefore, the RUC stated they will not review CPT codes 31000 and 31002 or comment on them further at this time. Another commenter noted the absence of non-facility payment for CPT code 31002, stating that this code should be valued in the non-facility setting.

Response: We appreciate the commenters for their feedback, specifically as it relates to the lack of non-facility payment for CPT code 31002 and may consider the commenters' feedback in future rulemaking.

After consideration of public comments, we are finalizing our proposal not to nominate nasal sinus irrigation (CPT codes 31000 and 31002) as potentially misvalued.

(10) Portable X-Ray Services (HCPCS codes R0070, R0075)

In the CY 2025 PFS final rule, we acknowledged that several portable x-ray (PXR) suppliers and trade organizations continue to express longstanding concerns with how payment is established for transportation services related to PXR as described by HCPCS codes R0070 and R0075 (89 FR 97809). We also noted interested parties' request for greater consistency in the pricing of these services (89 FR 97809 through 97810). We suggested that interested parties may best engage with the MACs on these issues by appropriately reporting cost data in the MAC requested format. We also recognized that we should maintain consistency in pricing these services that are more indicative of changes in costs that occur yearly. In the proposed rule, we sought comments on whether we should assign national pricing under the PFS for PXR transportation services; specifically, for HCPCS code R0070 (Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen) and HCPCS code R0075 (Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen). We believed that national pricing would be conducive to ensuring consistency in payment rates across localities and also create payment stability for these services.

To nationally price HCPCS codes R0070 and R0075, we could use reference codes that have only PE values and no work RVUs because these codes describe only the transportation services associated with PXR. Since these codes are currently paid using contractor pricing, we could also analyze the average MAC payment for them to inform national pricing. For example, we observed that HCPCS code

R0070 was priced between $215 to 230 per service while HCPCS code R0075 was priced between $80 to 90 per service. Using these valuations could help to inform us of potential crosswalk codes to maintain consistency with the rates currently being paid. By converting the dollar payment for HCPCS codes R0070 and R0075 from Medicare Part B claims data into RVUs through the usage of our current conversion factor under the PFS, we identified potential crosswalk codes. For HCPCS code R0070, we could use a crosswalk to CPT code 93243 (External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report), which has a total national non-facility payment rate of $226.43 for CY 2025, and for HCPCS code R0075, we could use a crosswalk to CPT code 92582 (Conditioning play audiometry), which has a total national non-facility payment rate of $86.69 for CY 2025.

We requested comments from the public on whether we should consider national pricing for HCPCS codes R0070 and R0075, as well as whether these potential crosswalk codes would appropriately value these services, and any other factors we should consider.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters mentioned they greatly appreciated CMS' recent updates to the Medicare Claims Processing Manual (MCPM) Chapters 13 and 23, consolidating prior manual chapters into chapter 13, section 90.3. Commenters stated the updates to the MCPM on the periodic review process, annual updates, and payment rate publication timelines, have allowed for greater transparency and collaboration between PXR suppliers and the MACs. However, given the recently updated MCPM guidelines that both MACs and PXR are operating under, commenters urged CMS to allow this process to proceed before establishing any national payment rate for HCPCS codes R0070 and R0075. Commenters state that establishing a national payment rate would fail to capture accurate resource costs for PXR services in rural and underserved areas. They also noted that national payment rates would not sufficiently account for geographic cost differences and would rely on inaccurate cost data.

Furthermore, we received a few comments in response to our comment solicitation to potentially crosswalk HCPCS codes R0070 and R0075 to CPT codes 93243 and 92582, respectively. Commenters opposed the idea and stated any attempt to crosswalk would not accurately reflect the costs of these

services and potentially prevent access for our beneficiaries. In conclusion, all commenters were in support of operating under our updated MCPM guidelines for PXR services and oppose any establishment of national rates for CY 2026.

Response: We appreciate commenters for their support on CMS' recent updates to the Medicare Claims Processing Manual (MCPM) chapters 13 and 23, consolidating prior manual chapters into chapter 13, section 90.3. We note that these recent MCPM manual updates are a result of longstanding concerns with how payment is established for transportation services related to PXR and we look forward to the increased collaboration between PXR suppliers and the MACs. Additionally, we recognize the MCPM manual updates for PXR services are recent and understand the preference for the framework to operate before establishing any national payment rates. However, we do want to also acknowledge that historically, under the PFS, various sources of information have helped inform payment for specific services used to establish direct PE inputs. These different methods can be used to derive pricing for specific products that are more reflective of their costs, such as performing market research, utilizing the invoice submission process, and reviewing cost information on Medicare claims. Therefore, the flexibility to use a variety of cost information to develop national rates under the PFS ratesetting methodology can help maintain resource costs for services and access to care for our beneficiaries.

After consideration of public comments, we will take into account the concerns raised by commenters to help inform any establishment of a national payment rate in future rulemaking. We also look forward to the continued dialogue between the MACs and PXR suppliers under the updated MCPM guidelines.

(11) Cryoablation Therapy to Treat Postoperative Pain

An interested party requested we establish a code to describe the additional intraoperative time required by the surgeon to perform adjunctive cryoablation therapy for postoperative pain management. According to the interested party, intraoperative cryoablation therapy is performed as a supplemental procedure alongside primary surgical procedures to provide postoperative pain relief for up to 60 days. The therapy works by freezing nerves near the surgical site without causing permanent damage, temporarily blocking pain signals during the patient's recovery period. The interested party stated that this procedure requires an additional 20 to 30 minutes of intraoperative time for the surgeon beyond the

primary surgical procedure. The interested party referenced clinical evidence highlighting the use of intraoperative cryoablation to reduce the need for opioids in postsurgical patients, as well as recent guideline recommendations.[29,30]

Currently, there is no specific code to account for the additional physician work associated with intraoperative cryoablation therapy. According to the nomination letter, we included the Cryo Nerve Block Therapy (CryoNB) on the list of devices eligible for temporary additional payments under the Non-Opioids Prevent Addiction in the Nation (NO PAIN) Act[31] in the CY 2025 OPPS final rule (89 FR 94353 through 94354). However, the interested party stated barriers still exist for physician adoption mainly because there is currently no code to account for the 20 to 30 additional minutes of physician work associated with the intraoperative administration and delivery of cryoablation therapy.

Also, the interested party stated that many practitioners incorrectly interpret Medicare's anesthesia rules as prohibiting payment for extra professional services when the same surgeon provides ancillary cryoablation therapy.[32] According to the nominator, while CMS typically does not allow separate payments for anesthesia services when the same physician performs both the surgical procedure and anesthesia, this limitation does not apply to cryoablation therapy for postoperative pain management.[33] However, according to the interested party, ongoing confusion regarding this policy's application creates an unnecessary barrier to cryoablation procedures that could reduce or replace opioid use for Medicare beneficiaries.

The interested party stated that establishment of a G-code for physician work associated with intraoperative cryoablation therapy for postoperative pain would facilitate greater access for patients who require or prefer non-opioid alternatives for pain relief. The interested party further stated that such a G-code would help promote patient access to this alternative to opioids by clarifying that Medicare anesthesia rules do not apply to cryoablation for postoperative pain when furnished by the same surgeon.

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[29] Miller DL, Hutchins J, Ferguson MA, Barhoush Y, Achter E, Kuckelman JP. Intercostal Nerve Cryoablation During Lobectomy for Postsurgical Pain: A Safe and Cost-Effective Intervention. Pain Ther. 2025 Feb;14(1):317-328. doi: 10.1007/s40122-024-00694-3.
[30] Dunning J, Burdett C, Child A, Davies C, Eastwood D, Goodacre T, Haecker FM, Kendall S, Kolvekar S, MacMahon L, Marven S, Murray S, Naidu B, Pandya B, Redmond K, Coonar A. The pectus care guidelines: best practice consensus guidelines from the joint specialist societies SCTS/MF/CWIG/BOA/BAPS for the treatment of patients with pectus abnormalities. Eur J Cardiothorac Surg. 2024 66(1):ezae166.
[31] CY 2025 OPPS Final Rule, 89 Fed. Reg. 93912, 94354 (Nov. 27, 2024) (CMS specifically affirmed that "the CryoNB System meets the statutory requirements and should be paid separately under this provision.").
[32] See Medicare NCCI 2024 Coding Policy Manual, Chapter 13, pgs. 6-7 (revised Jan. 1, 2025), available at: https://www.cms.gov/files/document/13-chapter13-ncci-medicare-policy-manual-2025finalcleanpdf.pdf.
[33] AHA Coding Clinic®, Q3 2024 vol. 11, no. 3 (effective with discharges Aug. 1, 2024).

We sought public comments on whether a new G-code is needed to account for the additional intraoperative time required to perform cryoablation therapy, including service elements and valuation of work and practice expense, including potential crosswalk codes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Numerous commenters were in favor of establishing a G-code as they emphasized intraoperative intercostal nerve cryoablation being a clinically valuable adjunct therapy that significantly improves patient outcomes. Many commenters reported benefits to patients' post-operative recovery and pain control, particularly in reducing opioid use, and shorter length of stays. They emphasized that these benefits extend well beyond the immediate postoperative period and contribute to broader public health goals of reducing opioid dependence.

Commenters identified several significant barriers limiting their ability to offer this therapy. Commenters reported that cryoablation adds 20 to 40 minutes of surgical time, with most commenters noting an average of 20 to 30 minutes of additional surgical and anesthesia time per case that is not reflected in current coding. Commenters also stated that the procedure requires specialized equipment and staff training that is not reflected in the resource costs associated with the primary surgical procedure. Also, the commenters stated that misinterpretation of Medicare anesthesia rules and global surgery package guidelines has led many providers to incorrectly believe that cryoablation cannot be billed separately.

Based on this information, commenters made three recommendations: (1) establish a G-code for intraoperative cryoablation that recognizes the additional physician work and time required to perform this procedure during surgery; (2) include clarifying language in the CY 2026 PFS or OPPS proposed rules to align physician billing guidelines with established American Hospital Association (AHA) coding guidance; and (3) confirm that Medicare anesthesia rules and global surgery rules do not apply to cryoablation performed for postoperative pain management.

Regarding the request that CMS establish a G-code to account for the additional physician work and time required to perform cryoablation, a commenter suggested CPT codes 32664 (*Thoracoscopy, surgical; with thoracic sympathectomy*) or 64809 (*Sympathectomy, thoracolumbar*) as reasonable

crosswalks for establishing appropriate valuation, given similarities in time, intensity, and resources. Another commenter suggested valuing the code using crosswalk to an add-on (ZZZ Global) code within 20 to 35 minutes of intra-service time such as: CPT code 33268 (*Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)*), CPT code 32667 (*Thoracoscopy, surgical; with therapeutic wedge resection (eg, mass or nodule), each additional resection, ipsilateral (List separately in addition to code for primary procedure)*), CPT code 32507 (*Thoracotomy; with diagnostic wedge resection followed by anatomic lung resection (List separately in addition to code for primary procedure)*), CPT code 33509 (*Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic*), CPT code 64643 (*Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)*), CPT code 64645 (*Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)*), and CPT code 64913 (*Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)*).

In addition to creating a payment code, commenters requested that CMS provide billing guidance in the CY 2026 PFS or OPPS Proposed Rules that aligns with the established AHA coding guidance, explicitly allowing surgeons to bill separately for cryoablation when performed for postoperative pain management. According to the commenter, this intervention serves a distinct therapeutic purpose with different techniques, equipment, and clinical objectives than standard anesthesia administration.

Commenters also recommended that CMS confirm that Medicare global surgery rules and anesthesia rules do not restrict billing for intraoperative cryoablation. These commenters explained that cryoablation is a separate surgical objective from the primary procedure and should not be bundled, noting that this procedure serves a distinct clinical purpose separate from anesthesia.

Overall, commenters stated that, adopting these changes would align with the intent of the NO PAIN Act (section 4135 of the Consolidated Appropriations Act (CAA), 2023) and CMS' recognition of cryoablation devices in recent payment rules, ultimately accelerating adoption of evidence-based, non-opioid pain management strategies while supporting innovation in patient care. Commenters noted that as

cryoablation represents a significant advancement in non-opioid care pain management, removing these barriers by implementing their recommendations can expand patient access to safe non-opioid alternatives, and align payment policy with strong clinical evidence supporting improved outcomes and reduced opioid use.

Response: We agree with commenters that an intraoperative intercostal nerve cryoablation is a clinically valuable adjunct therapy that significantly improves patient outcomes, with many reporting benefits to patients' post-operative recovery and pain control. Thus, we are finalizing the creation of a new add-on G code, HCPCS code G0571 (*Intraoperative nerve(s) cryoablation for post-surgical pain relief (list separately in addition to code for primary service)*) to be billed with a surgical procedure to account for additional time and resources required to perform cryoablation. For an add-on G code, we believe that CPT code 64645 (*Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)*), with an intra-service time of 25 minutes and a work RVU of 1.39, is an appropriate crosswalk reference to capture the additional intraoperative time and complexity involved in furnishing this service. As this service would only be furnished in the Facility setting, we are not finalizing the direct PE inputs based on this crosswalk reference.

Also, we note that the cryoablation device is paid as a qualifying non-opioid treatment for pain relief under the OPPS/ASC as authorized by the NO PAIN Act. In the context of and in accordance with the NO PAIN Act, cryoablation for the purpose of postoperative pain management is separately billable by the interventionalist/surgeon performing another procedure.

(12) Sleep Study (CPT code 95800)

For CY 2026, an interested party re-nominated CPT code 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone, and sleep time*). This code was recently nominated two times as potentially misvalued in the CY 2024 PFS proposed rule (88 FR 52283 through 52284) and the CY 2025 PFS proposed rule (89 FR 61618 through 61619).

For the CY 2024 and CY 2025 PFS final rules, we stated that we were unable to properly assess whether CPT code 95800 is potentially misvalued and further stated that we could not identify whether

disposable or reusable home sleep apnea testing (HSAT) devices are more commonly used based on the evidence submitted with the original nominations and subsequent comments that CMS received. To confirm whether disposable devices were more commonly used, the nominator commissioned a consulting group to conduct an independent survey of sleep medicine providers, developed with input from the American Academy of Sleep Medicine (AASM), which found that 60 percent of procedures reported with CPT code 95800 used fully disposable HSAT equipment among respondents who reported this service in 2023.

The nominator stated that CPT code 95800 is misvalued because there has been a fundamental shift in clinical practice from reusable equipment to disposable HSAT devices, but the current direct practice expense (PE) inputs still reflect the older reusable technology assumptions. The nominator stated that CMS currently models' payment for CPT code 95800 based on the use of a reusable sleep testing device (the WatchPAT 200) with a consumable component (WatchPAT probe), but the survey data demonstrates that the majority of procedures now use fully disposable devices like the WatchPAT ONE. According to the nominator, this misalignment between current medical practice and the direct PE inputs has resulted in inaccurate direct practice expenses for CPT code 95800 and created access challenges for Medicare beneficiaries, particularly in rural and remote areas, since the payment structure does not accurately reflect the actual costs and technologies used in contemporary sleep study practices. The nominator recommended deleting the current equipment codes for reusable devices and adding a new supply code for the disposable WatchPAT ONE device to ensure that Medicare reimbursement rates align with the "typical procedure" methodology that now involves disposable rather than reusable equipment. For more details, we refer to the CY 2025 PFS final rule (89 FR 97741 through 97743). Also, we refer readers to the submitted nomination, which is posted in the public use files for this proposed rule available on our public website under PFS **Federal Regulation** Notices at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

TABLE A-C2: LISTING OF NOMINATOR'S PRACTICE EXPENSE ITEMS FOR ADDITION OR DELETION TO CPT CODE 95800

Current Equipment/Supply Code	Equipment/Supply Description	Nonfacility/Office Equipment/Supply PE Cost	Recommended Equipment/Supply Status
EQ335	WatchPAT 200 unit with strap, cables, charger, booklet and patient video	$4.71	Delete
EQ336	Oximetry and Airflow Device	$4.55	Delete
SD263	WatchPAT pneumo-opt s|p probes (reusable)	$73.32	Delete
SD362	WatchPAT ONE device (disposable)	$98.20	Add

While we appreciate the survey, we note that there are several limitations that can influence the survey's generalizability, validity, and reliability. Some key limitations include a small sample of 25 complete responses with a low 12 percent survey engagement rate, and methodological constraints such as the short 17-day survey period.

Given that we only have access to the nominator's summary of their internal data and survey results with a few notable limitations, we propose to maintain the current direct PE supply and equipment inputs for CPT code 95800. We did not propose to nominate the code as potentially misvalued. We welcomed public comments, published studies, other surveys, and data on whether the typical procedure described by CPT code 95800 now involves the use of a disposable HSAT device rather than reusable equipment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to not nominate CPT code 95800 as potentially misvalued and advised us to continue monitoring this issue. They recommended CMS hold any adjustments to CPT code 95800 until after the RUC submits its final recommendations for the CY 2027 PFS proposed rule.

Response: We appreciate commenters for their feedback and look forward to reviewing the RUC recommendations per our standard process.

Comment: A commenter stated that the manufacturer and distributor of home sleep apnea testing (HSAT) devices conducted an independent survey of HSAT providers that specifically evaluated the practices of sleep medicine providers that billed CPT code 95800 in the prior year (2023). The purpose of the Survey was to evaluate the relative utilization of reusable vs. disposable HSAT devices used in

procedures reported with CPT code 95800. The survey, which was developed with the input of the American Academy of Sleep Medicine (AASM) and was under the control of KNG Health through its design and implementation, concluded that 60 percent of procedures reported with CPT code 95800 used fully disposable HSAT equipment.

The commenter noted that there were 25 complete responses to their provider survey, which CMS cited as a small sample size. The commenter stated that CMS did not recognize that the 25 responses represented the practices and volume of 35 sleep practitioners, since certain respondents were practice administrators answering on behalf of multiple sleep practitioners. The commenter noted that the number of respondents is common in RUC surveys valuing new CPT codes. In addition, the commenter pointed out that the provider survey targeted a universe limited only to a random sample of accredited sleep providers who billed CPT code 95800 in 2023 for a Medicare FFS patient. According to the commenter, because of these specific parameters, the reported device use of the 35 total clinician respondents was more representative of the typical 95800 procedure. The commenter stated that the survey response rate of 12 percent of a targeted survey universe materially exceeds the typical RUC survey response rate used by CMS to value new or modified services. The commenter cited a U.S. Government Accountability Office (GAO) report found that the median response rate of RUC surveys was 2.2 percent, and more than 10 percent of RUC surveys had under 30 respondents.[34] The commenter continued noting CMS's concern on the short 17-day period in the field, which according to the commenter is generally consistent with the in-field period for a RUC survey, where surveys must be distributed, collected, analyzed, and developed into recommendations to the RUC within approximately one month. The commenter described the RUC surveys as in the field for 2 to 3 weeks, consistent with their own survey. The commenter stated that they engaged an independent health consulting firm with experience in conducting provider surveys, as the manager of the survey. They also stated that they received assistance from the AASM CPT and RUC advisors, as well as health policy staff, who provided updates and additions to the survey before it was distributed. They stated that the survey was not overly restrictive in scope, as it gathered data on types of

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[34] *GAO, Medicare Physician Payment Rates: Better Data and Greater Transparency Could Improve Accuracy, GAO15-434, Medicare Physician Payment Rates: Better Data and Greater Transparency Could Improve Accuracy | U.S. GAO.*

devices used, device brands, practice size, and typical HSAT volume across multiple HSAT testing codes and that survey recipients were not limited to a specific manufacturer's customers or sales contacts.

In conjunction with the details of the survey, the same commenter provided full-year sales data from 2024, which showed that more than 52 percent of WatchPAT tests were performed with disposable devices. They also included data from the first half of 2025, which showed that more than 56 percent of WatchPAT tests used the disposable device rather than a reusable device confirming the trend of steadily increasing use of disposable HSAT devices. To reflect the shift in clinical practice associated with the use of disposable HSAT devices, the commenter provided an updated list of supply input changes.

TABLE A-C3: CPT CODE 95800 SUPPLY INPUTS

CPT Code	Category	Supply Code	Description	Price	Quantity	Supply Cost	Supply Status
~~95800~~	~~Accessory Procedure~~	~~SD263~~	~~WatchPAT pneumo-opt slp Probes~~	~~73.32~~	~~1~~	~~73.32~~	Delete
95800	Accessory Procedure	SD362	WatchPAT ONE device	98.20	1	98.20	Add
95800	Wound care, dressings	SG005	adhesive remover, liquid (Detachol) (0.67ml uou)	2.4	1	2.4	Retain
95800	Wound care, dressings	SG078	tape, surgical occlusive 1in (Blenderm)	0.007	8	0.056	Retain
95800	Pharmacy, NonRx	SJ053	swab-pad, alcohol	0.04	5	0.2	Retain
95800	Office Supply, Grocery	SK057	paper, laser printing (each sheet)	0.02	2	0.04	Retain
95800	Infection Control	SM021	sanitizing cloth-wipe (patient)	0.07	2	0.14	Retain
95800	Infection Control	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	0.07	2	0.14	Retain

They stated that establishing direct PE inputs consistent with the adjusted equipment and supply inputs described previously for code 95800, while retaining current labor and malpractice inputs, would result in an accurate valuation that reflects the costs associated with disposable HSAT device services.

Response: We appreciate all of the information provided, both as part of the initial request and alongside public comments. After additional consideration, we agree with commenters that the survey conducted by the device manufacturer provides additional data that augments what we received as part of the RUC recommendation. As the practice of medicine evolves to in some cases reflect a shift from reusable to disposable HSAT equipment, we believe that the direct practice expense inputs should reflect those changes. Therefore, based on the information provided by commenters regarding the outdated nature of the code and supply input pricing, and the additional information provided in public comments, we are finalizing an update to the PE inputs as described in Table A-C3 for CY 2026.

We inadvertently omitted the RUC requests listed below (see Table A-C4) from the proposed rule. We acknowledge receipt of these requests; however, because these codes were not addressed in the CY 2026 PFS proposed rule, we may consider them in future rulemaking.

TABLE A-C4: LISTING OF RUC REQUESTS

CPT Codes	Description
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour.
31525	Laryngoscopy direct, with or without tracheoscopy; diagnostic, except newborn.
31231	Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure).
69210	Removal impacted cerumen requiring instrumentation, unilateral.
17250	Chemical cauterization of granulation tissue (ie, proud flesh).
93792	Patient/caregiver training for initiation of home international normalized ratio (INR) monitoring under the direction of a physician or other qualified health care professional, face-to-face, including use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results.
93793	Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed.
G0250	Physician review, interpretation, and patient management of home INR testing for patients with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests.
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.

Lastly, we received several comments nominating codes as potentially misvalued for review and revaluation by CMS. These code families were not addressed in the CY 2026 PFS proposed rule; therefore, these comments are out of scope for this final rule. However, we note that commenters are welcome to submit these codes by February 10 of the coming year for consideration as potentially misvalued services in the CY 2027 PFS proposed rule. See the discussion at (TO BE ADDED) for more information on how to submit a nomination for a potentially misvalued code.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006), the CY 2021 PFS final rule (85 FR 84502), and the CY 2024 PFS final rule (88 FR 78861 through 78866) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed and assigned to categories established through notice and comment rulemaking. Under the process we established beginning in CY 2003, we evaluated whether a service should be assigned to the Medicare Telehealth Services List and designated as *Category 1:* Services similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List or *Category 2:* Services that were not similar to those on the current Medicare Telehealth Services List.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID-19 pandemic. This new category described services that were added to the Medicare Telehealth Services List during the PHE, for which there was likely to be clinical benefit when furnished via telehealth, but there was not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis ultimately needed to meet the criteria under Category 1 or 2 to be permanently added to the *Medicare Telehealth* Services List. To add specific services on a Category 3 basis, we would conduct a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth.

In the CY 2024 PFS final rule (88 FR 78861 through 78866), we consolidated these three categories and implemented a revised 5-step process for making additions, deletions, and changes to the

Medicare Telehealth Services List (5-step process), beginning for the CY 2025 Medicare Telehealth Services List. The 5-step process review criteria are set forth in the CY 2024 PFS final rule (88 FR 78861 through 78866), includes the following steps: (1) Determine whether the service is separately payable under the PFS; (2) Determine whether the service is subject to the provisions of section 1834(m) of the Act; (3) Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3); (4) Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking; and (5) Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system. Rather than categorizing a service as "Category 1", "Category 2," or "Category 3," each service is now assigned a "permanent" or "provisional" status. A service is assigned a "provisional" status if it meets steps 1, 2, and 3 of our review process, and, if while there is not enough evidence to demonstrate that the service is of clinical benefit, there is enough evidence to suggest that further study may demonstrate such benefit.

b. Update to Modify the Medicare Telehealth Services List and Review Process

Section 1834(m)(4)(F)(ii) of the Act requires that the Secretary establish a process that provides, on an annual basis, for the addition or deletion of services to the definition of telehealth services for which payment can be made when furnished via telehealth under the conditions specified in section 1834(m) of the Act. As specified at § 410.78(f), except for a temporary policy that was limited to the PHE for COVID-19, we make changes to the list of Medicare telehealth services through the annual PFS rulemaking process. Our current 5-step review process reflects the stepwise method by which we consider requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning with the CY 2025 Medicare Telehealth Services List (88 FR 78861 through 78871).

We proposed, beginning for the CY 2026 Medicare Telehealth Services List, to revise the 5-step review process for reviewing requests to the Medicare Telehealth Services List. Based on feedback from interested parties, we believe that we need to simplify our telehealth list review process by focusing our

review on whether the service can be furnished using an interactive telecommunications system. The current 5-step review process has proven to be unclear for requestors. Interested parties, including requestors, have emphasized that it is difficult to ascertain the level of clinical evidence needed for a service with a provisional designation to be redesignated permanent. Additionally, for new services or services with low utilization, interested parties have had a difficult time providing peer-reviewed evidence applicable to the service and/or the Medicare beneficiary patient population. Lastly, based on feedback from interested parties and our own internal review, the 5-step process insufficiently accounts for the vital role of professional judgment exercised by physicians and other practitioners. We continue to believe that physicians and other practitioners, given their in-depth knowledge of their beneficiaries' clinical needs, are best positioned to exercise their professional judgment in determining whether a service can be safely furnished via telehealth and whether furnishing a service via telehealth will provide clinical benefit justifying its use.

Therefore, we proposed to remove step 4 (Consider whether the service elements of the requested service map to the service elements of services on the list that has a permanent status described in previous final rulemaking) and step 5 (Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system) from our review criteria and retain steps 1 through 3 (detailed later in this section). Under this update, services on the Medicare Telehealth Services List would no longer be designated "permanent" or "provisional". All services listed or added on the Medicare Telehealth Services List would be considered included on a permanent basis. Note, we would still reserve the right to remove services included on the Medicare Telehealth Services List based on internal review or feedback received from interested parties in accordance with section 1834(m)(4)(F)(ii) of the Act and (42 CFR 410.78(f)). We noted in the CY 2026 PFS proposed rule (90 FR 32593 through 32597), if finalized, that all codes currently on the list (provisional or permanent) would remain on the Medicare Telehealth Services List. Because we had already determined that services with a "provisional" designation satisfy the standards represented in steps 1 through 3 in prior rulemaking cycles, we do not believe further review would be required to justify their inclusion on the Medicare Telehealth Services List under the revised

process. We noted in the CY 2026 PFS proposed rule to continue to request information from interested parties about service(s) that may be appropriate for addition to or deletion from the list of Medicare telehealth services and their effects on beneficiary access, safety, and quality of care.

We proposed to retain steps 1 through 3 and eliminate steps 4 through 5 because we believe that the standards represented in Steps 1 through 3 alone are sufficient guardrails to ensure that only services separately payable under the PFS, subject to the provisions of section 1834(m) of the Act, and capable of being furnished using an interactive telecommunications system are considered Medicare telehealth services. For additional information, these steps are further discussed in the CY 2024 PFS final rule (88 FR 78861 through 78866). We do not believe steps 4 through 5 are necessary, because as discussed in the proposed rule, we believe the complex professional judgment of the physician or practitioner is sufficient to ensure a service can be safely furnished via telehealth and that the service will be clinically beneficial to the beneficiary. We believe that the determination to utilize the complex professional judgment of the physician or practitioner will better allow practitioners to determine if telehealth is appropriate for that specific Medicare beneficiary and that specific clinical scenario.

We expect that physicians and other practitioners would consider the entirety of the circumstances, including the clinical profile and needs of the beneficiary, to determine the appropriate modality for furnishing the service. This specification is similar to the requirements set forth for the process by which we update the list of covered surgical procedures in Medicare when furnished within an ambulatory surgical center (ASC) (also called the ASC covered procedures list (CPL)), which were established in the 2021 OPPS Final Rule (85 FR 86148 through 86149). In addition, this specification is similar to our policy regarding the in-person visit requirements for telehealth behavioral health services ("…the practitioner is not precluded from scheduling in-person visits at a more frequent interval, should such visit be determined to be clinically appropriate or preferred by the patient" (86 FR 65057)) and for audio-only telehealth services ("practitioners should always use their clinical judgment in deciding to furnish services via telehealth, including in the patient's home, to ensure that appropriate care is being delivered; including scheduling in-person care as needed" (89 FR 97761)). We strive to balance the goals of increasing practitioner and patient choice of service modality with the consideration of patient safety for all Medicare beneficiaries. Notably, the addition of a service to the Medicare Telehealth Services List

does not mean that it is appropriate to be furnished via telehealth to every Medicare beneficiary in every clinical scenario—as always, the physician or practitioner should use his or her complex professional judgment to determine the appropriate service modality on a case-by-case basis. As technology advances and more services may be safely furnished via telehealth and paid under the PFS, it is increasingly important for physicians or practitioners to exercise their professional judgment in determining the generally appropriate service modality for their patients to receive a service.

We believe our update to remove steps 4 through 5 of the 5-step review process would expand and build upon our intent to simplify and reduce the administrative burden of submission and review of services to the Medicare Telehealth Services List. We believe our policy would allow patients and physicians or practitioners to determine the most appropriate service modality for an individual patient while continuing to ensure patient safety. As discussed in the proposed rule, physicians and other practitioners are best positioned to make patient-specific service modality determinations. Physicians and other practitioners have the greatest familiarity with and understanding of the needs of their individual patients and will use their complex professional judgment to determine whether a service can be safely furnished via telehealth, given their patients' clinical profiles and needs, among other essential considerations.

We believe physicians and other practitioners would consider important safety factors when determining the appropriate service modality for their specific beneficiaries. We continue to encourage the review and use of clinical practice guidelines, peer-reviewed literature, and similar materials that illustrate the typical setting of care, population of beneficiaries, and clinical scenarios that practitioners would encounter when furnishing the Medicare Telehealth service using only interactive, two-way audio-video communications technology or two-way, real-time audio-only communication technology for services furnished to a patient in their home, as permitted in accordance with § 410.78(a)(3). We proposed to refine the regulatory process for adding services to or deleting services from the Medicare Telehealth Services List by removing steps 4 and 5 and maintaining the current steps 1 through 3. The steps are listed in detail in this section:

Step 1. Determine whether the service is separately payable under the PFS.

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS because, as further discussed in CY 2024 PFS final rule (88 FR 78861 through 78866), Medicare telehealth services are limited to those services for which separate Medicare payments can be made under the PFS. Before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should therefore first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files).

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

If we determine at step 1 that a service is separately payable under the PFS, we apply step 2 under which we determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. Section 1834(m) of the Act provides payment to a physician or other practitioner for a service furnished via an interactive telecommunications system, notwithstanding that the furnishing physician or practitioner and patient are not in the same location, at the same amount that would have been paid if the service was furnished without the telecommunications system. We have historically interpreted this to mean that only services that are ordinarily furnished with the furnishing physician or practitioner and patient in the same location can be classified as a "telehealth service" for which payment can be made under section 1834(m) of the Act. Given that there may be a range of services delivered using certain telecommunications technology that, though they are separately payable under the PFS, do not fall within the definition of telehealth service set forth in section 1834(m) of the Act, the aim of step 2 is therefore to determine whether the service at issue is, in whole or in part, inherently a face-to-face service. Services that fall outside the definition of telehealth services generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we therefore review during this step 2 whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient and physician or practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

Step 3 is corollary to step 2 and is used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from requesters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed.

Additionally, we proposed to simplify our Medicare Telehealth Services List review process by removing the distinction between provisional and permanent services and focusing our review on whether the service can be furnished using an interactive, two-way audio-video telecommunications system. We sought comments on our proposal to refine the Medicare Telehealth Services List review process. We also invited comments regarding safety and/or quality concerns. We would like to re-emphasize that a service's presence on the Medicare telehealth list does not indicate that we believe that telehealth may be appropriate in all circumstances; instead, we rely on physicians and other practitioners to use their professional judgment to make appropriate determinations based on the needs of the individual patient.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters generally supported our proposal to simplify our review process to

add services to the Medicare Telehealth Services List, including removing steps 4 and 5 and eliminating the provisional and permanent categories. The commenters appreciated that this simplified process would reduce the administrative burden, enhance provider flexibility, and provide greater clarity, stability, and predictability for providers. The commenters also supported our emphasis on clinical judgment and supporting practitioners in practicing, to the extent possible, on the most clinically sophisticated tasks and making the most of their professional training. The commenters also supported that this policy change could improve access for beneficiaries while preserving patient-centered care, without compromising patient safety. Some commenters requested that we monitor the impact of this policy change to ensure beneficiary safety, quality, and access. A few commenters did not support our proposal because they believe that the elimination of steps 4 and 5 of the review process does not support a consistent, evidence-based safeguard to ensure that the outcomes of telehealth services are comparable to those of in-person services.

Response: We appreciate the commenters for their feedback. We continue to believe that the professional judgment of the physician or practitioner is sufficient to ensure a service can be safely furnished via telehealth and that the service will be clinically beneficial to the beneficiary. We believe that the determination to utilize the professional judgment of the physician or practitioner will better allow practitioners to determine if telehealth is appropriate for that specific Medicare beneficiary and that specific clinical scenario. We will continue to consider the feedback from interested parties for future rulemaking.

After consideration of public comments, we are finalizing as proposed.

c. Requests to Add Services to the Medicare Telehealth Services List for CY 2026

We received several requests to add various services to the Medicare Telehealth Services List, effective for CY 2026, some of which we believe would meet the revised criteria for being added to the Medicare Telehealth Services List. That is, we reviewed these services and found that they would meet the criteria of the 3-step process in section D(1)(b) of the proposed rule. The requested services are listed in Table A-D1.

Consistent with the deadline for our receipt of code valuation recommendations from the American Medical Association's Relative Value Scale Update Committee (AMA RUC) and other

interested parties (83 FR 59491) and with the process set forth in prior calendar years, for CY 2026, requests to add services to the Medicare Telehealth Services List must have been submitted to and received by CMS by February 10, 2025. Consistent with the deadline for our receipt of code valuation recommendations from the AMA RUC and other interested parties (83 FR 59491) and with the process set forth in prior calendar years, for CY 2027, requests to add services to the Medicare Telehealth Services List must be submitted to and received by CMS by February 10, 2026. The deadline for each request to add a service to the Medicare Telehealth Services List must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the Medicare Telehealth Services List, including where to send these requests, and to view the current Medicare Telehealth Service List, see our website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

TABLE A-D1: CY 2026 REQUESTS FOR ADDITION TO THE MEDICARE TELEHEALTH SERVICES LIST

Category	HCPCS	Short Descriptor
Multiple-Family Group Psychotherapy	90849	Multiple family group psytx
Group Behavioral Counseling for Obesity	G0473	Group behave couns 2-10
Infectious Disease Add-On	G0545	Inherent visit to inpt
Auditory Osseointegrated Sound Processor	92622	Dx aly aud oi snd prcsr 1st
	92623	Dx aly aud oi snd prcsr each
Dialysis	90935	Hemodialysis one evaluation
	90937	Hemodialysis repeated eval
	90945	Dialysis one evaluation
	90947	Dialysis repeated eval
Telemedicine E/M	98000	Synch audio-video new sf 15
	98001	Synch audio-video new low 30
	98002	Synch audio-video new mod 45
	98003	Synch audio-video new hi 60
	98004	Synch audio-video est sf 10
	98005	Synch audio-video est low 20
	98006	Synch audio-video est mod 30
	98007	Synch audio-video est hi 40
	98008	Synch audio-only new sf 15
	98009	Synch audio-only new low 30
	98010	Synch audio-only new mod 45
	98011	Synch audio-only new high 60
	98012	Synch audio-only est sf 10
	98013	Synch audio-only est low 20
	98014	Synch audio-only est mod 30
	98015	Synch audio-only est high 40
Home INR Monitoring	G0248	Demonstrate use home INR mon

The following is a discussion of the requests received for the addition of services to the Medicare Telehealth Services List:

(1) Multiple-Family Group Psychotherapy

We received a request to add CPT code 90849 (*Multiple-Family Group Psychotherapy*) to the Medicare Telehealth Services List. This code describes the provision of psychotherapy to multiple adult or adolescent patients and their family members simultaneously. This code was requested to be added in the CY 2022 PFS Final Rule, but we did not add it to the Medicare Telehealth Services List at the time because these services were not separately payable and had a restricted payment status, indicating that claims must be adjudicated on a case-by-case basis when furnished in-person (86 FR 65052). In the CY 2023 PFS Final Rule (87 FR 69404), we finalized a change in the procedure status indicator for CPT code 90849, which is now assigned an A for active status meaning that the service is now separately payable under the PFS. Based on our review, we believe this service now meets step 1 of our review process because it is currently assigned status indicator A, meets step 2 of our review process because it is a service ordinarily furnished with the furnishing practitioner and patient in the same location and therefore is subject to the provisions of section 1834(m) of the Act, and meets step 3 because that all elements of this service may be furnished using an interactive telecommunications system as defined in § 410.78(a)(3). Therefore, we proposed to add this service to the Medicare Telehealth Services List. We requested public comments on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the addition of CPT code 90849 (Multiple-Family Group Psychotherapy) to the Medicare Telehealth Services List. Commenters cited that the service described by CPT code 90849 demonstrates its ability to be furnished via telehealth due to being similar to other forms of group psychotherapy that are included on the Medicare Telehealth Services List. Commenters also cited that telehealth platforms are well-equipped for this type of service and that the availability of this service via telehealth particularly benefits families in areas that do not have clinicians readily available or for families that may have constraints that inhibit coordinating in-person care.

Response: We appreciate the commenters for their feedback.

After consideration of public comments, we are finalizing as proposed to add Multiple-Family Group Psychotherapy services (CPT code 90849) to the Medicare Telehealth Services List, beginning in CY 2026

(2) Group Behavioral Counseling for Obesity

We received a request to add CPT code G0473 (*Face-to-face behavioral counseling for obesity, group (2 to 10), 30 minutes*) to the Medicare Telehealth Services List. This code includes a 30-minute group session that consists of a dietary assessment, counseling, and behavioral therapy, as well as one face-to-face visit per week for each week for the first month, one face-to-face visit every other week for months 2 through 6, and one face-to-face visit per month for months 7 through 12 (if an individual loses 3kg in the first 6 months). Based on our review, we believe this service meets step 1 of our review process because it is currently assigned status indicator A, meets step 2 of our review process because it is a service ordinarily furnished with the furnishing practitioner and patient in the same location and therefore is subject to the provisions of section 1834(m) of the Act, and meets step 3 because that all elements of this service may be furnished using an interactive telecommunications system as defined in § 410.78(a)(3). Therefore, we proposed to add this service to the Medicare Telehealth Services List. We requested public comments on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the addition of CPT code G0473 (*Face-to-face behavioral counseling for obesity, group (2 to 10), 30 minutes*) to the Medicare Telehealth Services List, stating that this service may be furnished via telehealth due to being similar to other similar group counseling codes that are already included on the Medicare Telehealth Services List. The commenters stated that when this service is furnished via telehealth specifically, patients may experience reduced stigma, enhanced privacy, improved adherence, and family involvement that can enable dietary and lifestyle planning to support long-term participation in the 12-month Intensive Behavioral Therapy for Obesity program.

Response: We appreciate the commenters for their feedback.

After consideration of public comments, we are finalizing as proposed to add Group Behavioral

Counseling for Obesity (CPT code G0473) to the Medicare Telehealth Services List, beginning in CY 2026.

(3) Infectious Disease Add-On

We received a request to add CPT code G0545 (*Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent*)) to the Medicare Telehealth Services List. This code can include service elements such as disease transmission risk assessment and mitigation, public health investigation and analysis, and complex antimicrobial therapy counseling. Based on our review, we believe this service meets step 1 of our review process because it is currently assigned status indicator A (meaning that the service is separately payable under the PFS), meets step 2 of our review process because it is a service ordinarily furnished with the furnishing practitioner and patient in the same location and therefore is subject to the provisions of section 1834(m) of the Act, and meets step 3 because that all elements of this service may be furnished using an interactive telecommunications system as defined in § 410.78(a)(3). Therefore, we proposed to add this service to the Medicare Telehealth Services List. We requested public comments on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the addition of HCPCS code G0545 to the Medicare Telehealth Services List. The commenters supported this addition because this service is similar to other add-on codes that are currently on the Medicare Telehealth Services List and stated that the presence of this service on the Medicare Telehealth Services List would enhance beneficiary access. The commenters stated that there is a gap in access to infectious disease clinicians, who have expertise in risk assessment, public health investigation, and complex therapies without unnecessary delays or travel for patients, particularly in areas with limited in-person infectious disease resources.

Response: We appreciate the commenters for their feedback.

After consideration of public comments, we are finalizing as proposed to add the Infections Disease Add-on (CPT code G0545) to the Medicare Telehealth Services List, beginning in CY 2026.

(4) Auditory Osseointegrated Sound Processor

We received a request to add CPT codes 92622 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes*) and 92623 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)*) to the Medicare Telehealth Services List. Based on our review, we believe these services meet step 1 of our review process because they are currently assigned status indicator A (meaning that the service is separately payable under the PFS), meet step 2 of our review process because they are services ordinarily furnished with the furnishing practitioner and patient in the same location and therefore subject to the provisions of section 1834(m) of the Act, and meet step 3 because that all elements of these services may be furnished using an interactive telecommunications system as defined in § 410.78(a)(3). Therefore, we proposed to add these services to the Medicare Telehealth Services List. We requested public comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the addition of CPT codes 92622 and 92623 to the Medicare Telehealth Services List. The commenters supported this addition because this service is similar to other audiology codes that are currently on the Medicare Telehealth Services List. Commenters also stated that telehealth platforms are well-equipped for this type of service, eliminating barriers related to geography, transportation, and physical mobility.

Response: We appreciate the commenters for their feedback.

After consideration of public comments, we are finalizing as proposed to add Auditory Osseointegrated Sound Processor services (CPT codes 92622 and 92623) to the Medicare Telehealth Services List, beginning in CY 2026.

(5) Dialysis

We received a request to add dialysis procedures described by CPT codes 90935 (*Hemodialysis procedure with single evaluation by a physician or other qualified health care professional*), 90937 (*Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription*), 90945 (*Dialysis procedure other than hemodialysis (for example, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional*), and 90947 (*Dialysis procedure other than hemodialysis (for example, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription*) to the Medicare Telehealth Services List. These codes describe reviewing medical records, obtaining an interval history, performing an expanded problem focused or detailed physical examination, formulating and/or revising diagnosis and treatment plan(s) (moderate or high complexity medical decision-making), and discussing diagnosis and treatment. On either a single or two or more visits, the practitioner assesses the patient and response so far to dialysis, writes and/or reviews orders, and supervises dialysis.

We proposed not to add these services to the Medicare Telehealth Services List at this time, as we do not believe that we have enough information to determine if these services meet step 3 of the Medicare Telehealth review process. It is not clear under what clinical circumstances this service could be furnished via telehealth and how all service elements would be performed when furnished via telehealth. We sought comments on whether the elements of the service are capable of being delivered via an interactive telecommunication system as required for Medicare telehealth services under § 410.78(a)(3). We also sought comments regarding the service elements clinical staff at the originating site are performing and how these patient interactions compare to service elements that the professional may be furnishing via telehealth. When adding ESRD-related services (CPT codes 90963 through 90966, 90967 through 90970) to the Medicare Telehealth Service list in the CY 2015 (80 FR 41783) and CY 2017 (81 FR 80194) final rules with comment period, we noted the clinical examination of the access site must still be furnished face-to-face "hands-on" (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA. We sought comment to see if this requirement would also be appropriate for CPT codes 90935, 90937, 90945, and 90947 or if any other service elements need to be furnished "hands-on." We

noted in the proposed rule that we required more information to determine whether this requirement of a "hands-on" clinical examination by a physician, CNS, NP, or PA would inhibit furnishing these services via telehealth, or if a practitioner at the originating site could perform this requirement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: As requested, several commenters provided more information about under what clinical circumstances this service could be furnished via telehealth. The commenters provided information that these codes are generally used to treat critically ill, potentially hospitalized patients who are best treated in-person rather than via telehealth. These commenters acknowledged that there may be extremely limited circumstances in which patients in rural areas may benefit from these services being on the Medicare Telehealth Services List, but that in most cases, these patients would require an in-person visit. A commenter who had originally supported the addition of these codes has since determined that the addition of these services is no longer necessary.

We received a few comments requesting that we add these services to the Medicare Telehealth Services List, however, the commenters did not provide more information under what clinical circumstances this service could be furnished via telehealth and how all service elements would be performed when furnished via telehealth. A few commenters further requested the addition of these services, stating that some components of the service can be furnished via telehealth, and that the addition of these services can increase provider flexibility and increase access to care.

Response: We continue to believe that these services do not meet step 3 of the Medicare Telehealth review process. We are not persuaded that all service elements could be furnished via telehealth, since we did not receive this information. We look forward to reviewing additional information and considering this for future rulemaking.

After consideration of public comments, we are finalizing as proposed to not add these services to the Medicare Telehealth Services List.

(6) Home INR Monitoring

We received a request to add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List for CY 2026. This service, as described by HCPCS code G0248, encompasses a

face-to-face demonstration of the use and care of the INR monitor, obtaining at least one blood sample, providing instructions for reporting home INR test results, and documenting the patient's ability to perform testing and report results. In response to this request for the CY 2025 PFS proposed rule, commenters explained in detail that the interaction with the patient described by this service is generally delivered by individuals considered to be clinical staff and not a physician or practitioner as defined under section 1834(m)(4) of the Act. "Clinical staff" means someone who is supervised by a physician or other qualified health care professional and is allowed by law, regulation, and facility policy to perform or assist in a specialized professional service but does not individually report that professional service. After reviewing these comments and receiving additional information from interested parties, especially those that reminded us that the patient interactions for this service typically occur with clinical staff, it is clear that this is not a service that is generally furnished via a telecommunications system by a physician or a practitioner, as defined under section 1834(m)(4) of the Act, but rather is a technical part of a service delivered by clinical staff employed or otherwise providing services for a supplier. Indeed, the patient interaction portion of the service is valued under the PFS as typically involving the clinical staff of a supplier rather than the professional work of a physician or practitioner. Furthermore, there is no restriction on billing for this service and a physician/practitioner visit code on the same day, which suggests that the interaction between the clinical staff and the patient described by this service is severable from the kind of professional service that falls under the scope of section 1834(m) of the Act. We understand that before the broad adoption of telecommunications technology for patient interactions nearly 6 years ago, these interactions may have typically taken place in person, and we considered the request to add this service to the telehealth list in that context. However, the interaction described explicitly by the code does not indicate an interaction between the patient and a physician or other practitioner. Because such an interaction falls outside the scope of the definition of Medicare telehealth service, it does not meet step 2 of our review process. Therefore, we proposed not adding HCPCS code G0248 to the Medicare list of telehealth services. We requested public comments on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters, including suppliers of home PT/INR monitoring services,

requested additional clarifications regarding HCPCS code G0248 not meeting step 2 of the Medicare Telehealth Services review process.

Response: We would like to clarify that HCPCS code G0248, falls outside the scope of the definition of a Medicare telehealth service in section 1834(m) of the Act and so does not meet step 2 of our review process. This service is not subject to section 1834(m) of the Act. This service may include activities, including initial set-up and training, that are not typically or ordinarily furnished in-person. Because this service is delivered by clinical staff employed or otherwise providing services for a supplier, this service is not subject to the same rules concerning telehealth services that apply to physicians and practitioners.

After consideration of public comments, we are finalizing as proposed to not add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List.

(7) Telemedicine E/M Services

We received a request to add the telemedicine E/M services (CPT codes 98000 through 98015) to the Medicare Telehealth Services List. These services do not satisfy the criteria under Step 1 of our process. Specifically, they are not separately payable under the Medicare PFS, as they are currently assigned status indicator I (Not valid for Medicare purposes). Given that these services are not separately payable when furnished in person, they likewise will not be separately payable when furnished via telehealth. Therefore, this service does not meet Step 1 of our review process. We proposed not to add them to the Medicare list of telehealth services. We requested public comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters requested that we reconsider our proposal to not add these services to the Medicare Telehealth Services List, stating that reporting CPT codes with telehealth modifiers creates confusion and increases the risk of billing errors. Others supported our interpretation of section 1834(m) of the Act and our proposal not to add these services to the Medicare Telehealth Services List, as our interpretation of section 1834(m) of the Act requires that telemedicine services be reimbursed at parity with in-person visits. These commenters also appreciated maintaining equivalent billing requirements across all telehealth services and stated that this reduces administrative burden.

Response: These services do not meet Step 1 of our review process, and are not eligible to be added to the Medicare Telehealth Services List. We did not propose the removal of Step 1 of the review process. While CMS appreciates the comment, Step 1 is vital to ensuring that CMS is paying for telehealth services in accordance with section 1834(m) of the Act.

After consideration of public comments, we are finalizing as proposed to not add the telemedicine E/M services (CPT codes 98000 through 98015) to the Medicare Telehealth Services List.

(8) Clarification on DMHT/RPM/RTM

We have received a number of questions regarding Digital Mental Health Treatment (DMHT), Remote Physiologic Monitoring (RPM), and Remote Therapeutic Monitoring (RTM) services and the applicability of the telehealth rules. We would like to clarify that these services, which are inherently non-face-to-face, do not meet the definitions of section 1834(m) of the Act, fall outside the scope of the definition of Medicare telehealth service, and do not meet step 2 of our review process. These services are not subject to section 1834(m) of the Act.

Comment: A few commenters requested that we clarify if a telehealth place of service should be used for these services.

Response: No, under current regulation, a telehealth place of service would not be used for services that are not subject to section 1834(m) of the Act.

(9) Services Requested to be Transitioned from Provisional to Permanent

We received a number of submissions requesting for services on the Medicare Telehealth Services List designated as "provisional" to be designated as "permanent." We noted in the proposed rule that if our proposal to eliminate these designations is finalized, these codes will remain on the Medicare Telehealth Services List. If not, rather than selectively adjudicating only those services for which we received requests for potential permanent status, we believe it would be appropriate to complete a comprehensive analysis of all provisional codes currently on the Medicare Telehealth Services List before determining which codes should be made permanent. Therefore, we proposed to not make determinations to recategorize provisional codes as permanent at this time. For CY 2026, we proposed to revise the Medicare Telehealth Services criteria. We proposed to remove steps 4 and 5 from the review process. Using these revised criteria, we proposed to add 5 new codes to the Medicare Telehealth Services list that

are not on the CY 2025 Medicare Telehealth Services list. After consideration of the priorities discussed previously, we believe that these policies will increase the flexibility for physicians or other practitioners to exercise their complex professional judgment, factoring in patient safety considerations, and for flexibility for patients to choose the modality of care in which to receive services. The services we proposed adding to the Medicare Telehealth Services List are listed in TableA-D2.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to simplify our review process to add services to the Medicare Telehealth Services List, including removing steps 4 and 5 and eliminating the provisional and permanent categories, and supported our proposal to utilize this process for the CY 2026 PFS Final Rule. Commenters appreciated that this simplified process would reduce administrative burden, enhance provider flexibility, and provide greater clarity, stability, and predictability for providers. Commenters also supported our emphasis on clinical judgment and patient-centered care.

Response: We appreciate commenters for their feedback.

After consideration of public comments, we are finalizing as proposed.

(10) Deleted Services

In section II.I. of the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we proposed to delete HCPCS code G0136. We noted in the proposed rule that this code is currently on the Medicare Telehealth Services List, so it will also be deleted from the list if finalized.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters generally did not support the deletion of G0136 from the Medicare Telehealth Services List.

Response: Please see section II.X.4.a.(1) of this final rule for additional discussion of the HCPCS code G0136.

After consideration of public comments, we are not finalizing as proposed to delete HCPCS code G0136 from the Medicare Telehealth Services List.

TABLE A-D2: SERVICES FOR ADDITION TO THE MEDICARE TELEHEALTH SERVICES LIST FOR CY 2026

Category	HCPCS	Short Descriptor
Multiple-Family Group Psychotherapy	90849	Multiple family group psytx
Group Behavioral Counseling for Obesity		G0473 Group behave couns 2-10
Infectious Disease Add-On	G0545	Inherent visit to inpt
Auditory Osseointegrated Sound Processor	92622	Dx aly aud oi snd prcsr 1st
	92623	Dx aly aud oi snd prcsr each

d. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain frequency restrictions on how often physicians and other practitioners may furnish the service via telehealth. These include a limitation of one subsequent hospital care service furnished through telehealth every 3 days, added in the CY 2011 PFS final rule (75 FR 73317 through 73318), one subsequent nursing facility visit furnished through telehealth every 14 days, added in the CY 2011 PFS final rule (75 FR 73318), and one critical care consultation service furnished through telehealth per day, added in the CY 2017 final rule (81 FR 80198). In establishing these limits, we cited concerns regarding these patients' potential acuity and complexity.

We temporarily removed these frequency restrictions during the PHE for COVID-19. In the March 31, 2020 COVID-19 interim final rule with comment period (IFC) (85 FR 19241), we stated that we did not believe the frequency limitations for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations furnished via Medicare telehealth were appropriate or necessary for the duration of the PHE because this would have been a patient population who would have otherwise not had access to clinically appropriate in-person treatment. Although the frequency limitations resumed effect on May 12, 2023 (upon expiration of the PHE), through enforcement discretion during the remainder of CY 2023 and notice-and-comment rulemaking for CY 2024 and CY 2025, Medicare telehealth frequency limitations were suspended for CY 2025 (89 FR 97758 through 97760) for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations.

In the CY 2024 (88 FR 78877) and CY 2025 PFS final rules (89 FR 97758 through 97760), we solicited comments from interested parties on how physicians and other practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care

consultation services since the expiration of the PHE. As discussed in those final rules, many commenters supported permanently removing these frequency limitations, stating that they are arbitrary and re-imposing the limitations would result in decreased access to care; that physicians and other practitioners should be allowed to use their professional judgment to determine the type of visit, how many visits, and the type of treatment that is the best fit for the patient so long as the standard of care is met; and that lifting these limitations during the PHE has been instructive and demonstrates the value of continuing such flexibilities. Some commenters did not support removing these frequency limitations, citing patient acuity and safety. However, our analysis of claims data from 2020 to 2023 indicates that the volume of services that would be affected by implementing these limitations is relatively low; in other words, these services are not being furnished via telehealth with such frequency that, if the frequency limits were in place, they would be met or exceeded very often or for many beneficiaries. Claims data from 2020 to 2023 suggest that less than 5 percent of beneficiaries who received one or more of these services (subsequent care services in inpatient and nursing facility settings, and critical care consultations) received them as telehealth services. In addition, we have solicited comments on this policy for 2 years and have received overwhelming support for continuing this flexibility, with minimal commenters not supporting the removal of frequency limitations.

We believe that physicians and other practitioners, who have the greatest familiarity and insight into the needs of individual beneficiaries, can use their complex professional judgment to determine whether they can safely furnish a service via telehealth, given the entirety of the circumstances, including the clinical profile and needs of the beneficiary, to determine the appropriate service modality. We strive to balance the goals of increasing physician or practitioner and patient choice of service modality with consideration of patient safety for all Medicare beneficiaries. As technology advances and more services may be safely furnished via telehealth and paid under the PFS, it is increasingly important for physicians and other practitioners to exercise their professional judgment in determining the generally appropriate service modality for their patients to receive a service. Notably, the removal of these frequency limitations does not mean that these services are appropriate to be furnished via telehealth to every Medicare beneficiary in every clinical scenario—as always, the physician or practitioner should use his or her complex professional judgment to determine the appropriate service modality on a case-by-case basis.

We proposed to permanently remove frequency limitations on furnishing these services via telehealth for the following codes relating to Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services:

1. Subsequent Inpatient Visit CPT Codes:

● 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);

● 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*

● 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes:

● 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. when using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*);

● 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);

● 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of*

medical decision making. when using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.); and

● 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS Codes

● G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*.); and

● G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*.)

We solicited comments on these proposals, specifically additional information regarding potential concerns about patient safety and quality of care.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters generally supported the permanent removal of frequency limitations for Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services. The commenters stated that removal of these frequency limitations could enhance continuity of care, provide greater flexibility for clinicians, and allow clinicians to use their judgment in determining the appropriate cadence of telehealth interactions based on patient needs. Some commenters did not support our proposal, citing quality of care and safety concerns. One of these concerns was specifically for nursing residents, who may have complex health conditions that require careful monitoring and assessment, or conditions that make telehealth visits difficult. A few commenters supported our proposal but encouraged us to pair the removal of frequency limitations with safeguards such as enhanced claims monitoring or evidence-based utilization management.

Response: We appreciate the information from commenters regarding both patient safety concerns and concerns regarding supporting healthcare access. We believe that the complex professional judgment of the physician or practitioner will better allow practitioners to determine if the frequency of

telehealth services are appropriate for that specific Medicare beneficiary and that specific clinical scenario. We may consider additional safeguards for future rulemaking.

After consideration of public comments, we are finalizing as proposed.

2. Other Non-Face-to-Face Services Involving Communications Technology under the PFS

a. Direct Supervision via Use of Two-way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests described at § 410.32 and services incident to a physician's (or other practitioner's) professional service described at § 410.26 ("incident to" services), are required to be furnished under specific minimum levels of supervision by a physician or other practitioner. We define three levels of supervision at § 410.32(b)(3): General Supervision, Direct Supervision, and Personal Supervision. Notwithstanding the temporary measures implemented in response to the PHE for COVID-19 and extended thereafter, direct supervision has historically required the physician (or other supervising practitioner) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It has not historically been interpreted to mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. Again, notwithstanding the temporary measures implemented in response to the PHE for COVID-19 and extended thereafter, we have historically established this "immediate availability" requirement to mean in-person, physical, not virtual, availability (see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Direct supervision is required for various types of services, including most "incident to" services at § 410.26, many diagnostic tests at § 410.32, pulmonary rehabilitation services at § 410.47, cardiac rehabilitation and intensive cardiac rehabilitation services at § 410.49, and certain hospital outpatient services as provided at § 410.27(a)(1)(iv). In the March 31, 2020 COVID-19 IFC, we amended the definition of "direct supervision" for the duration of the PHE for COVID-19 (85 FR 19245 through 19246) at § 410.32(b)(3)(ii) to state that the necessary presence of the physician (or other practitioner) for direct supervision includes virtual presence through audio/video real-time communications technology. Instead of requiring the supervising physician's (or other practitioner's) physical presence, the amendment permitted a supervising physician (or other practitioner) to be considered "immediately available" through virtual presence using two-way, real-time audio/visual technology for diagnostic tests,

"incident to" services, pulmonary rehabilitation services, and cardiac and intensive cardiac rehabilitation services. We made similar amendments at § 410.27(a)(1)(iv) to specify that direct supervision for certain hospital outpatient services may include virtual presence through audio/video real-time communications. The CY 2021 PFS final rule (85 FR 84538 through 84540), CY 2024 PFS final rule (88 FR 78878), and CY 2025 PFS Final rule (89 FR 97764) subsequently extended these policies through December 31, 2025.

In the CY 2024 PFS proposed rule, we solicited comments on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we stated we were interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are providing the supervised service. We stated we were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy (88 FR 52302). As discussed in the CY 2024 PFS final rule (88 FR 78878), in the absence of evidence that patient safety is compromised by virtual direct supervision, we were concerned about an abrupt transition to our pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner. We noted that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as "incident to" services, and that physicians and/or other supervising practitioners, in certain instances, would need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. We acknowledged the utilization of this flexibility and recognize that many practitioners have stressed the importance of maintaining it. This flexibility has been available and widely utilized since the beginning of the PHE, and we recognized that it may enhance patient access.

In the CY 2025 PFS final rule (89 FR 97763), we acknowledged the utilization of this flexibility and stated we recognized that many practitioners have stressed the importance of maintaining it but were seeking additional information regarding potential patient safety and quality of care concerns. Given the importance of certain services being furnished under direct supervision in ensuring quality of care and

patient safety, and in particular the ability of the supervising practitioner to intervene if complications arise, we stated that we believe an incremental approach is warranted, particularly in instances where unexpected or adverse events may arise for procedures which may be riskier or more intense. In light of these potential safety and quality of care implications, and exercising an abundance of caution, we finalized the revision of the regulation at § 410.26(a)(2) to state that for the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall continue to include virtual presence through audio/video real-time communications technology (excluding audio-only): services provided "incident to" a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and services described by CPT code 99211 (*office and other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*).

In response to overwhelming support and requests to extend this policy permanently for a wider set of services than the ones that were finalized in the CY 2025 PFS final rules (89 FR 97758), we proposed to continue to build on this incremental approach to allow certain services to be provided under direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only). We proposed to permanently adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described at § 410.26, except for services that have a global surgery indicator of 010 or 090. This information can be found in the PFS PPRVU public use file (https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files). These global surgery indicators are defined in IOM Pub. 100-04, chapter 23, section 50.6 as 010 "Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable" and 090 "Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount." The purpose of excluding

these services is to ensure the quality of care and patient safety, and in particular, the ability of the supervising practitioner to intervene if complications arise, particularly in complex, high-risk instances where unexpected or adverse events may occur or for procedures that may be riskier or more intense where a patient's clinical status can quickly change. For such services, in-person supervision would be necessary to allow for rapid on-site decision-making in the event of an adverse clinical situation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters generally supported the permanent adoption of this policy and its revised definition, citing that virtual direct supervision does not inherently give rise to patient safety issues and that this policy could assist in a time of provider shortages. Some commenters supported the exclusion of codes with 010 and 090 global surgery services, citing that clinical staff supervised via virtual direct supervision do not perform complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures. A commenter requested that our definition be revised to remove the exclusion of services with 010 or 090 global surgery indicators and allow virtual direct supervision for all services paid under the PFS, since we have revised many telehealth policies to defer to clinical judgment throughout this final rule.

Some commenters suggested additional refinements to our proposal. The commenters provided conflicting recommendations to revise our definition to exclude services in which injected contrast is used. Some commenters recommended that we ensure that trained and authorized staff are present in the event of an adverse reaction to injected contrast, while other commenters stated additional clarifications in the definition are not needed, and submitted additional information supporting that virtual supervision of contrast administration is as safe as onsite supervision. The commenters also provided conflicting recommendations for the creation of a billing modifier, medical record documentation, or other means of data collection. Those who supported this recommendation stated that this would allow for better tracking, but those who did not support this recommendation stated that this revision would increase administrative burden without any benefit for patient care. The commenters provided other recommended revisions to this policy, including allowing audio-only supervision for facilities in low-connectivity regions. A few commenters did not support this proposal, stating that they had patient safety and care

concerns and believe that virtual direct supervision increases the risk for adverse outcomes.

Response: We appreciate the commenters for their support and suggestions on how we may refine our policy and will take them under consideration for future rulemaking. At this time, we believe that excluding services with 010 or 090 global surgery indicators is necessary to ensure the ability of the supervising practitioner to intervene if complications arise, particularly in complex, high-risk instances where unexpected or adverse events may occur or for procedures that may be riskier or more intense where a patient's clinical status can quickly change.

Comment: Some commenters did not support our proposal, opposing virtual direct supervision for auxiliary personnel who are authorized under their own statutory benefit category to bill Medicare for their services. Reiterating concerns previously expressed in comments in the CY 2025 PFS final rule, some commenters opposed our proposal to permanently allow for the virtual direct supervision because doing so would increase the amount of physician "incident to" billing (a Medicare outpatient provision that applies in the office or clinic setting and allows medical services to be provided by auxiliary personnel as an "incident to" the services of the billing practitioner and under their supervision) for services provided by PAs and NPs, which would obscure the extent to which PAs and NPs are actually performing the services. These commenters suggested that CMS allow for virtual supervision for only those medical professionals who are unauthorized to bill Medicare or, alternatively, establish a method through which CMS is able to collect information about the health professional actually providing the service under "incident to" billing.

Response: We appreciate the commenter's input regarding the appropriate attribution of services performed by PAs and NPs when those services are billed "incident to" a physician's service. However, we believe that any potential obscuration of the extent to which PAs and NPs are providing virtual direct supervision resulting from "incident to" billing is vastly outweighed by the flexibility and enhanced access to services resulting from allowing these practitioners to furnish virtual direct supervision. Regarding the commenters' suggestion that CMS establish a method through which we would collect the information of the health professional actually providing the service under "incident to" billing, we thank the commenters for their suggestion and may consider that through future rulemaking.

After consideration of public comments, we are finalizing as proposed.

We noted in the CY 2026 PFS proposed rule (90 FR 32593) that, similar to our guidance described in the proposed rule regarding Medicare Telehealth services, our definition of direct supervision (allowing "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only) for all services described at § 410.26, except for services that have a global surgery indicator of 010 or 090), does not mean that it is appropriate to allow virtual presence for every service for every Medicare beneficiary in every clinical scenario. As always, the physician or practitioner should use his or her complex professional judgment to determine the appropriate supervision modality on a case-by-case basis.

We proposed to revise the regulation at § 410.26(a)(2) to state that the presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters generally supported the permanent adoption of this policy and its revised definition.

Response: We appreciate commenters for their input.

After consideration of public comments, we are finalizing as proposed.

We proposed to revise § 410.32(b)(3)(ii) to state that the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the permanent adoption of this policy and its revised definition.

Response: We appreciate the commenters for their input.

After consideration of public comments, we are finalizing as proposed.

We noted in the proposed rule that because the definition of direct supervision applicable to cardiac, pulmonary, and intensive cardiac rehabilitation services relies on the definition of direct supervision set forth at § 410.32(b)(3)(ii), the definition of direct supervision for these services would similarly be modified to include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator. We solicited comments on applying this definition to the applicable services at § 410.32 and the applicable cardiac, pulmonary, and intensive cardiac rehabilitation services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters generally supported the permanent adoption of this policy and its revised definition.

Response: We appreciate the commenters for their input.

After consideration of public comments, we are finalizing as proposed.

We solicited comments on whether to adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described at § 410.26, except for services that have a 010, or 090 global surgery indicator. For each of the proposals, we also sought additional information regarding potential concerns about patient safety and quality of care for services that have a 000 global surgery indicator and if it is necessary to exclude these services from allowing the presence of the physician (or other practitioner) to include virtual presence through audio/video real-time communications technology (excluding audio-only). Global surgery indicator 000 is defined in IOM Pub. 100-04, chapter 23, section 50.6 as "Endoscopic or minor procedure with related preoperative and postoperative relative values on the day of the procedure only included in the fee schedule payment amount; evaluation and management services on the day of the procedure generally not payable". We noted that we believe that these services, which have no minimum postoperative period, do not have the same potential patient safety risk that services with a 010 or 090 global surgery indicator may have. We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments

we received and our responses.

Comment: A few commenters requested that services with a 000-day global period indicator to be excluded from virtual direct supervision restrictions, as these services are minor and could potentially be safely supervised virtually. Other commenters wanted us not to allow virtual direct supervision for services with a 000-day global period indicator, as some commenters believe that 000-day global services are of similar risk as services with a 010-day indicator. The commenters requested that we work with interested parties to categorize additional procedures that would be appropriate for virtual direct supervision.

Response: We appreciated the commenters for their feedback. Regarding concerns with the allowance of virtual direct supervision for services with a 000-day global services indicator, we do not agree that 000-day global services represent a similar level of risk as those with a 010-day indicator. 000-day global procedures are services that do not include any follow-up care included in the valuation, where as 010-day global services include the valuation of follow-up care extending out 10-days from the procedure. We believe this reflects significantly higher clinical intensity than 000-day global services. We welcome additional information from stakeholders on this policy.

After consideration of public comments, we are finalizing as proposed to not exclude services with a 000 global surgery indicator and to allow the presence of the physician (or other practitioner) to include virtual presence through audio/video real-time communications technology (excluding audio-only). The presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

b. Changes to Teaching Physicians' Billing for Services Involving Residents with Virtual Presence

As discussed in the CY 2025 PFS final rule (89 FR 97764 through 97765), in the CY 2021 PFS final rule (85 FR 84577 through 84585), we established a policy that after the end of the PHE for COVID-19, teaching physicians may meet the requirements set forth at section 1842(b)(7)(A)(i)(I) of the Act to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites located outside of OMB-

defined metropolitan statistical areas (MSAs). We made this location distinction consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas. We noted that this policy provides the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought, under section 1842(b)(7)(A)(i)(I) of the Act. In addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. We refer readers to the CY 2021 PFS final rule (85 FR 84577 through 84584) for a more detailed description of our specific concerns. At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service personally provided by residents to be paid for the service under the PFS, in locations that were within an MSA. This policy applied to all services, regardless of whether the patient was co-located with the resident or for services provided virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties expressed concerns regarding the requirement that the teaching physician be physically present with the resident when a service is furnished virtually (as a Medicare telehealth service) within an MSA. Some interested parties stated that during the PHE for COVID–19, when residents provided telehealth services, and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service,

available immediately in real-time, and had access to the electronic health record. After reviewing the public comments, we finalized a temporary policy that allowed the teaching physician to have a virtual presence in all teaching settings, but only in clinical instances when the service was furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment was sought, through audio/video real-time communications technology, in all residency training locations through December 31, 2024.

As stated in the CY 2025 PFS final rule (89 FR 97765), we were concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services. We also understood that teaching physicians gained clinical experience providing services involving residents with virtual presence during the PHE for COVID–19 and could help us to identify circumstances where the teaching physician can routinely provide sufficient personal and identifiable services to the patient through their virtual presence during the key portion of the Medicare telehealth service. We solicited comments and information to help us consider other clinical treatment situations where it may be appropriate to continue to permit the virtual presence of the teaching physician, while continuing to support patient safety, meeting the clinical needs for all patients and ensuring burden reduction without creating risks to patient care or increasing opportunities for fraud.

As summarized in the CY 2025 PFS final rule (89 FR 97764 through 97765), commenters encouraged us to establish this policy permanently and include in-person services to promote access to care, stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident. While we continue to consider clinical scenarios where it may be appropriate to permit the virtual presence of the teaching physician, we proposed to transition back to our pre-PHE policy, which would maintain the rural exception established in the CY 2021 PFS final rule recognizing the unique challenges and importance of expanding medical education opportunities in rural settings. We proposed not to extend our current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings through December 31, 2025, but

only when the service is furnished virtually (for example, a three-way telehealth visit, with the patient, resident, and teaching physician in separate locations). As always, documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology.

As discussed in the proposed rule, we were concerned that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID-19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act. Therefore, we believe that permitting Medicare payment to continue for this PHE flexibility is no longer necessary. As noted in the proposed rule, this proposal to not extend our current policy to allow teaching physicians to have a virtual presence for services furnished virtually aligns with our statutory obligations under section 1842(b)(7)(A)(i)(I) of the Act, which requires teaching physicians to provide appropriate oversight and personal involvement in resident-furnished services for which Medicare payment is sought.

We noted in the proposed rule that for services provided within MSAs, physicians must maintain physical presence during critical portions of all resident-furnished services to qualify for Medicare payment, not just in-person services, ensuring consistent oversight standards. Documentation requirements remain rigorous, with medical records needing to clearly demonstrate the teaching physician's physical presence during key service portions. However, as we discussed in the proposed rule, recognizing the unique challenges faced by rural healthcare providers, we maintain flexibility for services provided outside MSAs. In these rural settings, teaching physicians may continue utilizing audio/video real-time communications technology to fulfill the presence requirement, provided they maintain active, real-time observation and participation in the service. This geographical distinction aligns with our longstanding commitment to enhancing Medicare beneficiary access to covered services in rural areas.

We noted in the proposed rule that the proposal to not extend flexibilities for virtual services would not impact on teaching physicians' ability to provide virtual supervision of residents for

educational purposes. Teaching physicians retain the discretion to provide greater involvement in resident-furnished services and may determine when virtual presence is appropriate based on the specific services and the experience level of the residents involved.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal, stating that stronger oversight of residents in teaching settings is appropriate outside of a Public Health Emergency. However, the vast majority of commenters did not support our proposal. The commenters stated that over the past 5 years, this policy has proven to be effective, safe, and educationally sound. Both residents and teaching physicians have gained experience in providing virtual care, and continuation of this policy would support residents in being fully educated and prepared for virtual care in independent practice. In addition, continuation of this flexibility allows the ability for practitioners to pivot to virtual clinics for residents in cases of illness, inclement weather, or physical clinic closures. Ending this flexibility would also reduce care capacity, limit flexibilities in patient care, and would not allow for the full professional judgment of the teaching physician. Commenters also expressed concerns about the discontinuation of this policy and its impact on provider shortages and filling Graduate Medical Education slots for necessary vacancies in specialties such as psychiatry or pediatrics. Commenters also requested that this policy be expanded beyond services furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations, and include services where the resident and patient are in the same location with the teaching physician being present remotely. The commenters stated that if we were to discontinue the current flexibility, we should revise our proposed policy to include MSAs, as there are significant provider shortages in suburban and urban areas, or use a more expansive definition to include additional rural areas. Other commenters stated that the MSA requirement is arbitrary, as few teaching hospitals operate in rural areas.

Response: We agree with commenters that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident, and that this policy benefits teaching physicians, residents, and beneficiaries.

Comment: Commenters requested clarification regarding the proposed supervision policy change that appears to introduce a more restrictive standard for Medicare payment of resident-furnished services, imposing stricter requirements than those required for in-person services.

Response: We would like to clarify that we are not making any changes to the requirements currently in place for the supervision policy for teaching physicians. In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed, whether that service be furnished in-person or via telehealth.

After consideration of public comments, we are finalizing to permanently allow teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is (a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). This will continue to permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought, through audio/video real-time communications technology, for all residency training locations. As always, documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology. In accordance with section 1842(b)(7)(A)(i)(I) of the Act, the teaching physician must have personal oversight and involvement over the management of the portion of the case for which the payment is sought.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The percentage increase in the MEI for CY 2026 is 2.7 percent and is based on the expected historical percentage increase of the 2017-based MEI. In the CY 2026 PFS proposed rule (90 FR 32593), we proposed to update the MEI increase for CY 2026 based on historical data through the second quarter of 2025. Therefore, for CY 2026, the payment amount for

HCPCS code Q3014 (*Telehealth originating site facility fee*) is $31.85. Table A-D3 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

TABLE A-D3: THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$20.00
2003	3.0	$20.60
2004	2.9	$21.20
2005	3.1	$21.86
2006	2.8	$22.47
2007	2.1	$22.94
2008	1.8	$23.35
2009	1.6	$23.72
2010	1.2	$24.00
2011	0.4	$24.10
2012	0.6	$24.24
2013	0.8	$24.43
2014	0.8	$24.63
2015	0.8	$24.83
2016	1.1	$25.10
2017	1.2	$25.40
2018	1.4	$25.76
2019	1.5	$26.15
2020	1.9	$26.65
2021	1.4	$27.02
2022	2.1	$27.59
2023	3.8	$28.64
2024	4.6	$29.96
2025	3.56	$31.01
2026*	2.7	$31.85

*Reflects the most recent estimate of the CY 2026 MEI percentage increase and is updated in this final rule based on historical data through the second quarter of 2025.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed concern about the proposed increase to the telehealth originating site facility fee and its impact on beneficiary cost-sharing. Other commenters appreciated the proposal, as it accounts for inflation and maintains real value.

Response: We appreciated commenters for their feedback. Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

After consideration of public comments, we are finalizing as proposed.

4. Distant Site Requirements

We received many comments that requested CMS clarify policies related to, but separate from, our telehealth proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concerns regarding the perception of an expiring flexibility for telehealth practitioners to use their currently enrolled location instead of their home address when providing services from their home due to a lack of a proposal to extend this flexibility in the proposed rule. In these comments, interested parties voiced concerns about the safety and privacy of health professionals who work from home and furnish telehealth services. The commenters requested that CMS take steps to protect telehealth practitioners by adjusting enrollment requirements so that individual practitioners did not have to list their home addresses on enrollment forms. In the CY 2024 and CY 2025 PFS final rules we stated that, through CY 2025, we would permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

Response: Given that CMS issued an FAQ (located at https://www.cms.gov/medicare/quality/physician-compare-initiative/frequently-asked-questions) providing additional information on how to suppress street address details as providers continue to use their currently enrolled practice location instead of their home address when providing telehealth services from their home, we do not believe that additional "extensions" are required via rulemaking. We remind interested parties that we defer to State law regarding licensure requirements for distant site Medicare telehealth practitioners. In addition, we note that a separate Medicare enrollment is required for each State in which the practitioner furnishes and intends to bill for covered Medicare services. We would also like to clarify that in the future any updates to this policy will be issued via subregulatory guidance.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comments about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established

interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule. We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, regarding our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

a. Background

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other

physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult

procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the non-facility setting.

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least 1/3 of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes × 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concern over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We note that we are

obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we adjusted work RVUs to account for significant changes in time, we started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old-time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes

in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and suggested that our actions in adjusting the recommended work RVUs are inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we employed to identify potential values that reconcile the RUC-recommended work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2026 PFS proposed rule (90 FR 32593 through 32597) and the following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with CMS' reference to older work time sources and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with "CMS/Other" or "Harvard" work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times and note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing

values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Commenters recommended that CMS embrace the clinical input from practicing physicians when valid surveys were conducted and provide a clinical rationale when proposing crosswalks for valuation of services.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

We recognize that it would not be appropriate to develop work RVUs solely based on time, given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and this would not be accurate, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2026 PFS final rule, the following all share the same intraservice and total work time of 20 minutes: CPT codes 55715 (*Biopsy, prostate, each additional, MRI-ultrasound fusion or in-bore CT- or MRI-guided*), 92973 (*Percutaneous transluminal coronary thrombectomy aspiration mechanical*), 93571 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography*), 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month, first 20 minutes*), and 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care*

professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 20 minutes). However, these codes had very different proposed work RVUs of 1.05, 1.75, 1.80, 0.62, and 0.61, respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key references or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

We do not believe that our review process is arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). Regarding the commenter's concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms "reference services", "key reference services", and "crosswalks" as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we

necessarily must employ them in the identical fashion for the purpose of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, "crosswalk," to those cases where we made a comparison to a CPT code with the identical work RVU (83 FR 59515). We noted that we also occasionally make use of a "bracket" for code valuation. A "bracket" refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table A-E12 contains a list of codes and descriptors for which we proposed work RVUs for CY 2026; this includes all codes for which we received RUC recommendations by February 10, 2025. The finalized work RVUs, work time and other payment information for all CY 2026 payable codes are available on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/index.html*).

b. Efficiency Adjustment

(1) Background

We have historically relied on survey data provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) to estimate practitioner time, work intensity, and practice expense for the purpose of establishing RVUs for the codes used for payment under the PFS. As described in section II.C. of this final rule, CMS regularly revalues codes as part of its potentially misvalued codes initiative, as required by section 1848(c)(2)(K) of the Act, using RUC survey data that shows clinicians' estimates of how long a particular service takes to complete. In the CY 2025 PFS final rule, we summarized public comments that we had received expressing concerns with using RUC data as a source of valuation and identifying a need for empirical data in the context of valuing advanced primary care management services (89 FR 97898). In response to these comments, we indicated that we were open to alternative recommendations for how to price these

and other services, and that we would consider all options presented to us with a preference for information with empirical evidence behind it. We also reminded commenters that we do not exclusively rely on RUC recommendations and can receive data and recommendations from other outside sources as well.

In the CY 2026 proposed rule (90 FR 32399 through 32400) we discussed the challenges experienced with survey data. The limits of survey data are in part based on the nature of the surveys. There have been longstanding concerns about the use of surveys that have low response rates, low total number of responses, and a large range in responses, all of which may undermine the accuracy of recommendations relying on survey data.[35] For example, a Government Accountability Office (GAO) Report found that the median number of responses to surveys administered by the RUC for payment year 2015 was 52, the median response rate was only 2.2 percent, and 23 of the 231 surveys had under 30 respondents. Another study conducted compared operative times in the National Surgical Quality Improvement Project to RUC survey times, adjusted for patient variables, and found a wide variation in the median RVU per hour ratio for 11 surgical specialties, with the highest specialties overreporting (via RUC values) by 27 and 23 minutes per case. All surgical specialties showed overreporting in RUC survey times compared to operative times. This resulted in high RVU per hour payments for surgeons in those specialties.[36]

We stated that with such low response rates, we are concerned that those practitioners who respond to the RUC surveys may be fundamentally different than those clinicians who do not respond to the surveys. Widely read journals, such as the Journal for the American Medical Association, specify that for submitting authors, "survey studies should have sufficient response rates (generally greater than or equal to 60 percent), and appropriate characterization of non-responders to ensure that nonresponse bias does not threaten the validity of the findings."[37] The GAO report noted that the RUC has undertaken steps to mitigate the effects of possible biases; however, the report goes on to describe the potential conflicts of interest survey respondents may have, as those that serve Medicare beneficiaries would benefit from an

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[35] *https://www.gao.gov/products/gao-15-434.*
[36] Uppal, S., Barber, E. L., Reynolds, R .K., Rice, L. W., & Spencer, R. J. 2019. Discrepancies created by surgeon self-reported operative time and its impact on procedure relative value units (RVUs) and reimbursement. *Gynecologic Oncology, 154*, 14. *https://doi.org/10.1016/j.ygyno.2019.04.039.*
[37] Journal of the American Medical Association, Instructions for Authors. Available from: *https://jamanetwork.com/journals/jama/pages/instructions-for-authors*

increase in the relative values for the services they perform.[38] Another component of these surveys is the selection of another service code that is similar to the service in question. Since there are so many procedure, radiology, and diagnostic test codes, the selection of a high-valued service for potential comparisons, either by the specialty society administering the survey, or by respondents, could further bias results. Additionally, RUC surveys contain clinical vignettes, and expert reviewers have raised concerns that these clinical vignettes are not typical and thus may lead to biased recommendations that usually overinflate time spent on the service.[39] And as detailed in section II.B. of this final rule, we further articulate the particular challenges of using the recently completed PPI survey data, including the quality of the data, sampling variation, and lack of comparability to previous survey data—similar challenges that we have experienced over time with surveys estimating the time and work intensity of individual services, used to establish the work RVUs. We stated that CMS has historically had to rely on survey data due to a lack of other more reliable sources of information, but in recent years many new methods to identify empiric inputs used in valuation have been developed.[40]

We noted that in the CY 2024 PFS proposed rule (88 FR 78975 through 78982), we requested comments on how we may evaluate E/M services more regularly and comprehensively. We raised specific questions for commenters to consider, including whether the methods used by the RUC and CMS were appropriate to accurately value E/M and other HCPCS codes, and we requested that commenters provide specific recommendations on improving data collection and making better evidence-based and more accurate payments for E/M and other services. In response, as we summarized in the CY 2024 PFS final rule (88 FR 78977), commenters stated that the methods used do not lead to accurate valuation and that the problems lie with the nature of E/M services and the PFS's budget neutrality adjustment. They stated that the resources used in furnishing the work portion of E/M services are primarily a function of the time the clinician spends with the patient and, therefore, are not amenable to efficiency gains and that the valuation process is not responsive to efficiency gains, leading to passive devaluation of E/M services

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[38] *https://www.gao.gov/products/gao-15-434.*

[39] Zuckerman, S., K. Merrell, R. Berenson, et al. 2016. Collecting empirical physician time data: Piloting an approach for validating work relative value units. Report prepared for the Centers for Medicare & Medicaid Services. Washington, DC: The Urban Institute. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Collecting-Empirical-Physician-Time-Data-Urban-Report.pdf*

[40] National Academies for Sciences, Engineering, and Math. Improving Primary Care Valuation Processes to Inform the Physician Fee Schedule. Available from: *https://nap.nationalacademies.org/catalog/29069/improving-primary-care-valuation-processes-to-inform-the-physician-fee-schedule*

under the constraints of budget neutrality. At the time, we responded that we recognized that there are opportunities to improve how all services are valued and better account for resource variation for different types of care under the PFS.

We explained that for several years, we have been concerned about not accounting for the efficiencies gained in work RVUs for non-time-based services. Non-time-based codes, such as codes describing procedures, radiology services, and diagnostic tests, should become more efficient as they become more common, professionals gain more experience, technology is improved, and other operational improvements (including but not limited to enhancements in procedural workflows) are implemented. We highlighted, however, that there are often many years between a code's introduction and revaluation within the RUC process, with only a few hundred out of the more than 9,000 codes paid under the PFS considered for revaluation annually by the RUC. While there is significant variability in how often codes are reviewed by the RUC, on average, CMS estimates that there are 25.49 years since a code valuation has been reviewed by the RUC (this includes 5382 out of 9970 codes which were never reviewed). We stated that when we exclude from the average those codes that have never been reviewed, the average is 17.69 years since the last review of a code by the RUC. We noted that these numbers weight each code equally and the PFS itself is heavily weighted by utilization towards a much smaller number of often utilized codes.

Furthermore, even when a code is reviewed by the RUC, 2 to 3 years usually pass between when the survey data was collected and its use by CMS in setting rates becomes effective. We stated that in the intervening years without revaluation, we are most likely overvaluing codes by not accounting for these efficiencies gained in the valuation of work RVUs for non-time-based services. And even when recommendations have been submitted by the RUC to CMS as potentially misvalued codes from 2009 to 2025, the RUC only recommended a decrease in the physician time and resources for the codes 39 percent of the time.[41]

In the CY 2026 proposed rule (90 FR 32401) we explained how studies have demonstrated that CMS continues to overvalue non-time-based services. In a pilot project for CMS conducted by the Urban

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[41] American Medical Association. "AMA/ Specialty Society RVS Update Committee: An Overview of the RUC Process." Available from: *https://www.ama-assn.org/system/files/ruc-update-booklet.pdf.*

Institute in 2016,[42] which compared data obtained from electronic health records and direct observation, the ratios of fee schedule time to empirical time were often inflated, with the largest discrepancies in imaging and other test interpretations. In the study, the median ratio of PFS time to empiric intraservice physician time for CT and MRI scans was 2.13, for noninvasive cardiac testing was 4.00, and for mammography was 1.67. Another study compared estimated procedure time from anesthesia claims and the PFS time, and found that the mean estimated procedure time was 27 percent lower than the time used for PFS valuation.[43] Expert reviewers have attributed some of the discrepancies to automation and personnel substitution that has become prevalent in the time between when CMS adopted many codes and when those codes are revalued.[44] We noted that MedPAC, in their 2018 recommendations to Congress, recommended three options to offset these historic distortions, including passive devaluation: (1) an automatic reduction to the prices of new services and services with high growth rates; (2) an extension of the annual numeric target for CMS to reduce the prices of overpriced services; and (3) an across-the-board reduction to all fee schedule services other than ambulatory E&M services.[45] For reasons, as further described below in this section, we proposed a modified version of MedPAC's third option for procedures, radiology, and diagnostic tests.

We stated that section 1848(c)(2)(B)(ii)(I) of the Act provides that the Secretary shall, to the extent he determines to be necessary, adjust the number of RVUs to take into account changes in medical practice. We explained that we believe that many of the efficiency gains that historically may not have been fully reflected in the valuation of work RVUs for non-time-based services represent or have been caused by changes in medical practice. Therefore, to take into account changes in medical practice and better reflect the resources involved in furnishing services paid under the PFS, we proposed to establish an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services. We explained that our initial proposed approach

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[42] Zuckerman, S., K. Merrell, R. Berenson, et al. 2016. Collecting empirical physician time data: Piloting an approach for validating work relative value units. Report prepared for the Centers for Medicare & Medicaid Services. Washington, DC: The Urban Institute.*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Collecting-Empirical-Physician-Time-Data-Urban-Report.pdf*

[43] Crespin, Daniel, Teague Ruder, Andrew Mulcahy, Ateev Mehotra. "Variation in Estimated Surgical Procedure Times Across Patient Characteristics and Surgeon Specialties." JAMA Surg. 2022 May 1;157(5):e220099. doi: 10.1001/jamasurg.2022.0099.

[44] Zuckerman et al, 2016.

[45] MedPAC Report to Congress, 2018. Chapter 3: Rebalancing Medicare's Physician Fee Schedule Toward Ambulatory Evaluation and Management Services." Available from: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch3_medpacreport_sec.pdf.*

was designed to be conservative in nature, as we are concerned about making too many changes at once to the current methodology. We noted that we may, in the future, consider making additional corresponding updates to the direct PE inputs for clinical labor and equipment costs. Our proposal was based on our assumption that both the intraservice portion of physician time and the work intensity (including mental effort, technical effort, physical effort, and risk of patient complications) would decrease as the practitioner develops expertise in performing the specific service. As expertise develops, learning leads to enhanced familiarity with the various aspects of a service, variations in the anatomy of each patient, and confidence in the practitioner's own ability to handle unexpected challenges that arise.

For example, one cross-specialty observational study found that increased surgical experience was associated with significant reductions in operative time for coronary artery bypass grafting, total knee replacement, and bilateral reduction mammoplasty.[46] While this expertise in part develops as a practitioner accumulates years of experience following the culmination of training, it also accumulates across the entire health system with the creation of a new procedure or service that practitioners must grow accustomed to. We further noted that changes in medical practice such as enhancements in operational workflows and technology advancements after the introduction of a new procedure or service can further reduce the risk associated with the service and increase efficiencies. When a new surgical technique is introduced, operational workflows and procedures are based on previous experience with a similar service, which may not directly translate to the new procedure. We explained that these workflows generally evolve over time as experience grows, and tend to result in improvements, which make the service more efficient. This is consistent with systematic reviews demonstrating that with increased case volume and years of expertise, surgeons demonstrate decreased risk of poor outcomes.[47] We provided examples of other studies have found that with increased experience performing new procedures, clinicians demonstrate increased operational efficiency and decreased time. For example, one systematic review found that for clinicians newly introduced to robotic thoracic surgery, a reduction in operating time based on the increasing number of cases performed.[48] Another study concluded that for robotic

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[46] Maruthappu, Mahiben, Antoine Duclos, Stuart Lipsitz, Dennis Orgill, Matthew Carty. "Surgical Learning Curves and Operational Efficiency: A Cross-Specialty Observational Study." BMJ Open. 2015 Mar 13;5(3):e006679.
[47] *https://pubmed.ncbi.nlm.nih.gov/25072442/.*
[48] Power, Alexandra, Desmond D'Souza, Susan Moffatt-Bruce, Robert Merritt, Peter Kneuertz. "Defining the Learning Curve of Robotic Thoracic Surgery: What Does it Take? Surg Endosc. 2019 Dec;33(12):3880-3888. doi: 10.1007/s00464-019-07035-y. Epub 2019 Aug 2.

thoracic procedures, the hourly productivity increase for experienced and proficient surgeons ranged from 11.4 work relative value units/hour (+26 percent) for lobectomy to 17.0 work relative value units/hour (+50 percent) for segmentectomy.[49] We stated that these changes in practitioner experience, operational workflows, and new technologies in totality represent large-scale, system-wide changes in medical practice as described in section 1848(c)(2)(B)(ii)(I) of the Act that may not have been previously accounted for in the valuation of non-time-based codes. Given the relative infrequency of service revaluation under the PFS and the limitations of reliance on survey data, we are concerned that the RVUs we have established for codes paid under the PFS may not reflect these efficiencies accrued as practitioners gain experience, operational workflows improve, and new technology is adopted.

(2) Methodology for the Efficiency Adjustment

In the CY 2026 PFS proposed rule (90 FR 32401 through 32403) we described our proposed methodology to calculate the efficiency adjustment. We proposed using the Medicare Economic Index (MEI) productivity adjustment. The MEI is a measure of inflation faced by physicians with respect to their practice costs and general wage levels, and includes inputs used in furnishing physicians' services such as physician's own time, non-physician employees' compensation, rents, medical equipment, and more. Every year, the CMS Office of the Actuary (OACT) subtracts the MEI productivity adjustment from the MEI percent change moving average to calculate the final MEI update. The MEI productivity adjustment used for the final MEI update reflects the most recent historical estimate of the 10-year moving average growth of private nonfarm business total factor productivity, as calculated by the Bureau of Labor Statistics.[50] Every year, the productivity adjustment for the final MEI update is calculated by OACT based on historical data. For example, in 2026 the productivity adjustment for the final MEI update will reflect historical data through 2024. OACT incorporates a 10-year moving average to minimize yearly fluctuations in productivity associated with normal business cycles. We stated that the productivity adjustment to be applied to the proposed MEI percent change moving average for CY 2026 was listed in Table A-E1 (0.8 percent) of the CY 2026 PFS proposed rule, and it will be updated for the final rule based on the most up to date data. We explained that the MEI productivity adjustment is

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[49] *https://pubmed.ncbi.nlm.nih.gov/37562675/.*
[50] 87 FR 69709

substantively similar to the productivity adjustment required for the hospital inpatient prospective payment system (IPPS) and outpatient prospective payment system (OPPS) at sections 1886(b)(3)(B)(xi)(II) and 1833(t)(3)(F)(i) of the Act, respectively. The main difference is that the MEI productivity adjustment reflects historical data at the time of the CY update and the OPPS and IPPS productivity adjustments reflect a forecast to correspond to the FY update.

For CY 2026, we proposed to apply the efficiency adjustment using a look-back period of 5 years. We considered a couple initial look-back periods. We explained that despite the efforts to update valuation, many codes have never been revalued, and even for codes that have been revalued, there is, on average, more than 17 years since revaluation recommendations submitted by the RUC. Thus, using a look-back period of 17 years would help to account for the average amount of time that has elapsed since the last revaluation. However, using a look-back period of 17 years may be imprecise because, even when a code has been reviewed by the RUC, historic reliance on survey data may have skewed results and not properly accounted for efficiencies in the physician time and work RVU. Therefore, we also proposed to apply the efficiency adjustment to the codes that the RUC and CMS have reviewed within the look-back period of 5 years, including codes being proposed for revaluation this year, as many of the challenges discussed previously in this section, namely reliance on survey data, still apply. We realized that adjusting for the efficiencies gained would be a change in our payment methodology, and so as an initial conservative approach, we proposed a look-back of 5 years. We stated that this represents our intended cadence for updating the efficiency adjustment (3 years), plus an additional 2 years, since it has historically taken about 2 years to make changes to PFS valuation after we receive new recommendations from the RUC.

We recognized that over time, there may be variation in the efficiencies accrued service-by-service (for example, the previously cited research has identified that efficiencies have been gained more in minor procedures and radiology services than in major inpatient procedures). But because PFS intraservice time is higher than empirical intraservice time on average for studied non-time-based services,[51,52] we stated that we believe applying the efficiency adjustment to non-time-based services

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[51] Zuckerman et al, 2016.
[52] Crespin, Daniel, Teague Ruder, Andrew Mulcahy, Ateev Mehotra. "Variation in Estimated Surgical Procedure Times Across Patient Characteristics and Surgeon Specialties." JAMA Surg. 2022 May 1;157(5):e220099. doi: 10.1001/jamasurg.2022.0099.

more broadly, instead of applying it only to certain services that may be more likely to accrue efficiency gains, may help to improve the overall accuracy of our valuation of these services under the PFS. We further stated that a look-back period of 5 years is not intended to account for the full magnitude of previously unaccounted for efficiency gains in services paid under the PFS, and that we may consider making refinements to the efficiency adjustment in future rulemaking to better account for these gains. To implement this efficiency adjustment, we proposed to decrease the work RVUs and make corresponding changes to the intraservice physician time for codes describing non-time-based services by a factor equal to the MEI productivity adjustment, equivalent to if this factor had been applied every year over the past 5 years.

In the CY 2026 PFS proposed rule (90 FR 32402) we explained that this methodology yielded a proposed efficiency adjustment of 2.5 percent, which would be a downward (negative) adjustment for certain codes, for CY 2026. Given the 5-year look back period, the formula summed all productivity adjustments included in the final MEI updates from CY 2022-CY 2026. We noted that the CY 2026 productivity adjustment will be updated for the CY 2026 final rule to reflect more recent historical data from the Bureau of Labor Statistics.

TABLE A-E1: EFFICIENCY ADJUSTMENT FOR CY 2026

CY	MEI Productivity Adjustment (%)
2022	0.2
2023	0.5
2024	0.4
2025	0.6
2026*	0.8*
Efficiency Adjustment	**2.5%**

In the CY 2026 PFS proposed rule we used the proposed methodology described above, and included Table A-E2, which outlined examples of two different CPT codes that would be subject to the proposed efficiency adjustment. We noted that Table A-E2 was intended only as an illustrative example.

TABLE A-E2: EXAMPLES OF EFFICIENCY ADJUSTMENT

CPT Code	Short Descriptor	Current Intraservice Time (min)	Current Work RVU	Intraservice Time after Efficiency Adjustment (min)	Work RVU after Efficiency Adjustment
11200	Rmvl skin tags up to&inc 15	7	0.82	6.83	0.8
63047	Lam facetectomy & foramotomy 1 vrt sgm lumbar	90	15.37	87.75	14.99

We solicited comments on the initial look-back period and the use of the MEI productivity adjustment percentage values for calculation of the efficiency adjustment for 2026. We sought comments on whether adjustments should be made in future rulemaking to also adjust the direct PE inputs for clinical labor and equipment time that correspond with the physician time inputs.

In the CY 2026 PFS proposed rule (90 FR 32403) we stated that if the proposed methodology to calculate the efficiency adjustment was finalized for CY 2026, we proposed to apply the efficiency adjustment to the intraservice portion of physician time and work RVUs every 3 years. We stated that this timing would imply that the next efficiency adjustment after CY 2026 would be calculated and applied in CY 2029 PFS rulemaking, reflecting efficiency gains measured from 2027 through 2029. We also proposed to update and apply the proposed efficiency adjustment with a cadence of every 3 years to align with the other updates under the PFS, including updates to the Geographic Practice Cost Index (GPCI) and Malpractice (MP) RVUs, and explained that this would allow for streamlining so that interested parties can expect updates on a similar timeframe. We also sought comments as to whether or not efficiencies stop accruing for services after a predefined number of years.

In addition, we proposed applying this efficiency adjustment to non-time-based services that we expect to accrue efficiencies over time. We proposed to apply the adjustment to all codes except time-based codes, including but not limited to, E/M visits, care management services, behavioral health services, services on the CMS telehealth list, and maternity codes with a global period of MMM. This adjustment would apply to all codes that are assigned a procedure status of A (active), B (bundled), C (contractor/carrier priced code), I (not valid for Medicare purposes), N (noncovered service by Medicare), R (restricted coverage), and T (injections), and are not otherwise excluded. Included code families represent the procedures, diagnostic tests, and radiology services that CMS expects to accrue efficiencies over time as changes in medical practice occur, including changes in clinician expertise, workflows, and technology. We sought comments on the codes expected to accrue efficiencies over time. The full descriptions of these indicators can be found in the Medicare Claims Processing Manual, Chapter 23 at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c23.pdf*. Additionally, we noted that a list of the codes we proposed to apply this adjustment to could be found

under the Downloads section posted with the proposed rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

Finally, in the CY 2026 PFS proposed rule we explained that we understand that accruing efficiencies do not apply equally to all services, and that efficiencies gained over time may often apply more to services that take less time to perform. We further explained that efficiencies gained in services that could be performed many times per day such as cataract extractions, skin biopsies, and CT scans, allow the practitioner to perform more of those services in a given day. We sought comments on whether and how we should consider additional efficiencies for services that require less time to perform. Additionally, we sought comments on whether the introduction of new artificial intelligence has or will lead to otherwise unaccounted for efficiencies gained in specific services.

We also proposed that the public may submit nominations via the "Potentially Misvalued Codes" process, as described in section II.C. of this final rule, so going forward, if they believe the efficiency adjustment will lead to inaccurate physician time and work RVUs for a particular code. We stated that nominations submitted should include supporting information. For the reasons discussed previously in this section, we also proposed that CMS will place greater emphasis on "empiric" supporting information for the codes nominated, to avoid the limitations of using survey data. We provided proposed examples of empiric data may include electronic health record logs, operating room logs, and time-motion data and should be robust enough to achieve a high degree of assuredness as to accuracy and be inclusive of multiple types of practices (for example, inclusive of academic, health centers, and private practices wherever possible). We solicited comments on what kinds of data CMS should consider as valid, reliable, empiric information for this purpose.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that they believe we do not have the authority to apply an efficiency adjustment to non-time-based services, and that doing so would require a statutory change. The commenters stated that the application of the efficiency adjustment across all physician work RVUs is inconsistent with the approach envisioned by section 1848(c)(2) of the Act. The commenters stated that while section 1848(c)(2) of the Act may allow for extrapolation in some circumstances, such as where

data is not available, this would not be the case with the physician work RVUs that have been evaluated by the RUC on an ongoing basis. The commenters stated that reference to "such units" at section 1848(c)(2)(B)(ii)(I) of the Act appears to be to section 1848(c)(2)(B)(i) of the Act that states "relative values established under this paragraph for all physicians' services." The commenters stated that the implication of the statute is that the adjustments consider the individual circumstances of a procedure and not be applied across the board. A few commenters also stated that the efficiency adjustment proposal departs from the resource-based methodology that they state the Congress established for the PFS. A few commenters also stated the proposed efficiency adjustment undermines congressional intent to provide an increase in payment for physicians servicing Medicare beneficiaries.

Response: As stated in the CY 2026 PFS proposed rule (90 FR 32401), section 1848(c)(2)(B)(ii)(I) of the Act provides that the Secretary shall, to the extent he determines to be necessary, adjust the number of RVUs to take into account changes in medical practice. We believe that many of the efficiency gains that historically may not have been fully reflected in the valuation of work RVUs for non-time-based services represent or have been caused by changes in medical practice. To take into account changes in medical practice and better reflect resources involved in furnishing services paid under the PFS, we believe that our proposal to establish an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services, is appropriate.

Comment: We received many comments regarding the efficiency adjustment proposal. Concerns expressed by the commenters include:

- That the proposed efficiency adjustment proposal does not account for the complexities of individual procedures or the varying efficiencies across different specialties. The commenters stated that applying a uniform reduction could undermine the financial stability of practices, especially in rural and underserved areas where access to care is already limited. They state the proposed reduction could lead to reduced patient access to essential services, particularly in specialties facing workforce shortages. The commenters state the proposed efficiency adjustment prioritizes speed over quality of care and puts patients' safety at risk.

- That the proposal lacks transparency as to the data and methodology used to justify the efficiency adjustment. The commenters stated the proposal is arbitrary and capricious under section 5 USC 706(2)(A) of the Administrative Procedure Act (APA).

- That CMS should adopt a more targeted approach to incorporate efficiency gains within specific services or code families.

- That CMS should finalize a policy that will benefit all specialties and not just those that frequently bill time-based codes.

- That certain specialties have limited use of physician extenders. While some specialties gain efficiencies through the use of physician extenders, such as nurse practitioners and physician assistants, others are unable to leverage these physician extenders, thus limiting their potential for efficiency gains.

- Why certain specialties and code families (for example, E/M, behavioral health, care management, maternity, telehealth) are exempt, and that clear justification for the exemptions were not provided.

- A letter published by the Journal of the American College of Surgeons[53] indicated that for inpatient only procedures, surgical times are not declining, rather procedures had longer or similar operative times. Therefore, surgical and procedural services are not becoming more efficient over time, and in some cases, are becoming less efficient. Another study showed that in Q2 2025, "productivity is up 12% for physicians and 11% for advanced practice providers compared to two years ago."[54]

- Technology can, at times, increase the amount of physician time and cognitive skill required to perform a service. For example, a few commenters specifically mentioned that reading CT scans and MRIs today requires reviewing more images than it did in past years. Commenters stated CMS' assumption does not consider factors such as increases in care complexity, patient acuity, staff salaries, AI-generated insights, and the electronic health record ("EHR") systems that require the same or more resources than in the past.

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[53] Childers, Christopher P MD, PhD; Foe, Lauren M MPH; Mujumdar, Vinita JD; Mabry, Charles D. MD, FACS; Selzer, Don J MD, MS, FACS; Senkowski, Christopher K MD, FACS; Ko, Clifford Y MD, MS, MSHS, FACS, FASCRS; Tsai, Thomas C MD, MPH, FACS, Journal of the American College of Surgeons, Longitudinal Trends in Efficiency and Complexity of Surgical Procedures: Analysis of 1.7 Million Operations Between 2019 and 2023, Aug. 13, 2025.
https://journals.lww.com/journalacs/abstract/9900/longitudinal_trends_in_efficiency_and_complexity.1369.aspx.

[54] https://medcitynews.com/2025/09/physician-healthcare-medicare-payment-reimbursement/

- Adjusting physician work RVUs and intraservice time for all non-time-based codes, while exempting commonly performed services that are often used as key reference services, will cause disruption in the processes to update the Resource-Based Relative Value Scale (RBRVS) and ensure appropriate relativity of new and revised codes, and there would be rank-order anomalies within and across code families.

Response: We appreciate the commenters for their responses and appreciate the additional information. We understand the concerns raised by the commenters about the broad application of the proposed efficiency adjustment and the potential impact on specific specialties, patient access and care quality, particularly in rural and underserved areas. However, existing processes to account for efficiencies have been insufficient, as we described in the proposed rule (90 FR 32399 through 32403). Even when codes are revalued, it is based on survey data, with the corresponding shortcomings that we have articulated. In the CY 2026 PFS proposed rule (90 FR 32402), we recognized that while efficiencies may accrue more in some services compared to others, the fact that PFS intraservice time is higher than empirical intraservice time on average for studied non-time-based services,[55,56] means that applying the efficiency adjustment will more accurately reflect empiric data compared to not doing so.

In response to commenters concerned about technological advances in imaging and their impact on physician intraservice time, we note that imaging and other test interpretations have some of the highest mean empirical time to PFS intraservice time ratios of the services studied.[57] We appreciate that changes in technology may have varying impacts on different services, and welcome empiric data from commenters for future rulemaking.

In response to commenters' references to the published letter from the Journal of American College of Surgeons, we reviewed the letter[58] and note that while operative times increased for

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[55] Zuckerman, Stephen, Katie Merrell, Robert Berenson, Susan Mitchell, Divvy Upadhyay, Rebecca Lewis. "Collecting Empirical Physician Time Data: Piloting an Approach for Validating Work Relative Value Units." Dec 14, 2016. Available from: https://www.urban.org/research/publication/collecting-empirical-physician-time-data-piloting-approach-validating-work-relative-value-units.
[56] Crespin, Daniel, Teague Ruder, Andrew Mulcahy, Ateev Mehotra. "Variation in Estimated Surgical Procedure Times Across Patient Characteristics and Surgeon Specialties." JAMA Surg. 2022 May 1;157(5):e220099. doi: 10.1001/jamasurg.2022.0099.
[57] Zuckerman, Stephen, Katie Merrell, Robert Berenson, Susan Mitchell, Divvy Upadhyay, Rebecca Lewis. "Collecting Empirical Physician Time Data: Piloting an Approach for Validating Work Relative Value Units." Dec 14, 2016. Available from: https://www.urban.org/research/publication/collecting-empirical-physician-time-data-piloting-approach-validating-work-relative-value-units.
[58] Childers, Christopher P MD, PhD; Foe, Lauren M MPH; Mujumdar, Vinita JD; Mabry, Charles D. MD, FACS; Selzer, Don J MD, MS, FACS; Senkowski, Christopher K MD, FACS; Ko, Clifford Y MD, MS, MSHS, FACS, FASCRS; Tsai, Thomas C MD, MPH, FACS, Journal of the American College of Surgeons, Longitudinal Trends in Efficiency and Complexity of Surgical Procedures: Analysis of 1.7 Million Operations Between 2019 and 2023, Aug. 13, 2025. https://journals.lww.com/journalacs/abstract/9900/longitudinal_trends_in_efficiency_and_complexity.1369.aspx.

approximately 51 percent of CPT codes evaluated, they remained the same for approximately 38 percent of CPT codes and declined for approximately 11 percent. Furthermore, the stated increase in operative time given in the letter is 3.1 percent. We note that this information was published in a research letter, and therefore, we are not privy to the detailed methods used by the authors. However, we point commenters to a recent review of PFS intraservice times and times observed in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), and estimates derived from Medicare anesthesia claims which indicates that NSQIP median operative and anesthesia times are on average, 16 to 17 percent lower than PFS intraservice times.[59]

Additionally, we have seen that even after a change in valuation (such as a decrease in PFS time), the PFS intraservice time still is above empirically-observed time.[60] This is why, as we articulated in the proposed rule, we had discussed that CMS would preferentially consider empiric information submitted by interested parties, if they believe the efficiency adjustment led to incorrect valuation of the service. We believe that robust empiric data is important to avoid some of the shortcomings of survey data in accounting for efficiencies over time. We believe the efficiency adjustment will promote interested parties to submit more precise empiric data, which means that there will still be changes on a service-by-service basis, even if the efficiency adjustment itself affects all non-time-based services. As we proposed, interested parties can submit their requests as part of the Potentially Misvalued Codes initiative, as described in section II.C. of this final rule. We look forward to continued engagement with the public on this topic and are interested in information that could assist us in potentially refining this policy through future rulemaking.

Comment: Several commenters state that the RUC process already accounts for efficiency and applying an efficiency adjustment to codes recently reviewed would be redundant. The commenters stated that CMS should exempt newly established codes, codes established in recent years, or codes that have been recently reevaluated by the RUC.

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[59] Reid, Rachel O., Yu, Anthony, Hussey, Peter S., Hero, Joachim O., Klig, Cameron, Crespin, Daniel J., Swabe, Gretchen, Burgette, Lane F. "Surgical Procedure Time Comparisons, Comparing Physician Fee Schedule Intraservice Times with Real-World Times as Observed in National Surgical Quality Improvement Program Intraoperative Times and Anesthesia Claims, https://www.rand.org/pubs/research_reports/RRA3470-1.html.

[60] Reid, Rachel O., Yu, Anthony, Hussey, Peter S., Hero, Joachim O., Klig, Cameron, Crespin, Daniel J., Swabe, Gretchen, Burgette, Lane F. "Surgical Procedure Time Comparisons, Comparing Physician Fee Schedule Intraservice Times with Real-World Times as Observed in National Surgical Quality Improvement Program Intraoperative Times and Anesthesia Claims, https://www.rand.org/pubs/research_reports/RRA3470-1.html.

Response: We understand and appreciate the RUC for providing recommendations to CMS over the years. For many years, we did not have other sources of data to inform valuation of service paid under the PFS, and the RUC recommendations derived from surveys have been particularly important in the revaluation of services. However, studies have demonstrated that CMS continues to overvalue non-time-based services, with PFS time greater than mean procedure time by more than 20 percent,[61] which is in part due to the lack of both regular revaluing of all codes, and the nature of the survey data that has been the foundation of many of the RUC recommendations. The survey data used in RUC recommendations often have low response rates (as low as the single digits, even when publications for research usually require a response rate of at least 60, and appropriate characterization of non-responders to ensure that nonresponse bias does not threaten the validity of the findings[62]), the survey data is based on clinical vignettes that have raised concerns for bias.[63] This leads to the RUC Relativity Assessment Workgroup's Potentially Misvalued Services Project recommending the valuation of approximately 40 percent of identified services be decreased.[64] And even after a revaluation in the PFS, recent data demonstrates that PFS time still is higher than actual intraservice time.[65] This is why, to better recognize efficiencies gained, we proposed an efficiency adjustment. We welcome interested parties to submit empiric data that is robust in nature related to certain services, if they believe it is not correct to assume that efficiencies are gained over time, and we will consider whether or not reevaluation is needed as part of the Potentially Misvalued Codes initiative.

Additionally, we are persuaded by the commenters' feedback that it would not be appropriate to apply the efficiency adjustment to new services, given that practitioners would not be able to accrue efficiencies for services that are new in the first year. Therefore, we are exempting codes new for CY 2026 from the efficiency adjustment for CY 2026.

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[61] Crespin, Daniel, Teague Ruder, Andrew Mulcahy, Ateev Mehotra. "Variation in Estimated Surgical Procedure Times Across Patient Characteristics and Surgeon Specialties." JAMA Surg. 2022 May 1;157(5):e220099. doi: 10.1001/jamasurg.2022.0099.
[62] Journal of the American Medical Association, Instructions for Authors. Available from: https://jamanetwork.com/journals/jama/pages/instructions-for-authors.
[63] Zuckerman, Stephen, Katie Merrell, Robert Berenson, Susan Mitchell, Divvy Upadhyay, Rebecca Lewis. "Collecting Empirical Physician Time Data: Piloting an Approach for Validating Work Relative Value Units." Dec 14, 2016. Available from: https://www.urban.org/research/publication/collecting-empirical-physician-time-data-piloting-approach-validating-work-relative-value-units.
[64] American Medical Association. "AMA/ Specialty Society RVS Update Committee: An Overview of the RUC Process." Available from: https://www.ama-assn.org/system/files/ruc-update-booklet.pdf.
[65] Reid, Rachel O., Yu, Anthony, Hussey, Peter S., Hero, Joachim O., Klig, Cameron, Crespin, Daniel J., Swabe, Gretchen, Burgette, Lane F. "Surgical Procedure Time Comparisons, Comparing Physician Fee Schedule Intraservice Times with Real-World Times as Observed in National Surgical Quality Improvement Program Intraoperative Times and Anesthesia Claims, https://www.rand.org/pubs/research_reports/RRA3470-1.html.

Comment: Several commenters provided feedback on the exemption of E/M visits from the efficiency adjustment. Several commenters were in support of exempting E/M visits from the efficiency adjustment. A commenter stated that the current RVU evaluation process unduly favors non-E/M services, due to a variety of factors, including methodological and accuracy issues with the RUC surveys. Another commenter stated that while some E/M codes may be chosen based on time or medical decision making, they all heavily depend on time spent with the patient and thus are not amenable to efficiencies that otherwise apply to procedural or technology-oriented services. Since any given E/M code may be selected based on time, they are akin to other time-based services and thus properly excluded from the efficiency adjustment proposed by CMS. Conversely, a commenter stated that the proposed policy penalizes specialties with low time-based E/M utilization while benefiting specialties that predominantly bill time-based E/M services. The commenter continued to state that if finalized as proposed, the policy could create significant relativity distortions across the PFS.

Several commenters highlighted that CMS has made several increases to E/M work RVU values in recent years but did not make corresponding increases to the E/M components of global surgical packages. The commenters stated that this discrepancy has led to a loss of relativity within the fee schedule and undervalues global surgical packages. A few commenters stated the efficiency adjustment decreases the work value of bundled E/M visits, creating a discrepancy in payment between standalone and bundled E/M visits. They recommended CMS correct this inequity to maintain the relativity of code values.

Response: We appreciate the feedback and support from commenters. Based on section 1848(c)(2)(C)(i) of the Act, which requires the Secretary to determine a number of work relative value units for the service or group of services based on the relative resources incorporating physician time and intensity required in furnishing the service, including global surgical services, we continue to believe standalone E/M services should be exempt from the efficiency adjustment as detailed in the CY 2026 PFS proposed rule (90 FR 32593 through 32597). We also wish to clarify that the E/M visits are exempt from the efficiency adjustment, regardless of whether the E/M visit is billed based on time or medical decision making.

Comment: Several commenters stated that CMS should forego the efficiency adjustment, as intraservice times are increasing because patient's conditions are becoming more complex, stating that as the average age of patients increases, patient body mass index (BMI) rises, and the number of chronic conditions patients are diagnosed with increases.

Response: Over the last decade, we have updated PFS payment policies as appropriate and remain committed to improving how Medicare payment recognizes the resources involved in furnishing covered services. As a part of the CY 2014 PFS final rule, we recognized care management as a critical service contributing to better health outcomes for individuals (78 FR 74414 through 74427). Since then, we have implemented coding and payment for many care management services to better recognize the resources involved in furnishing medically necessary care management activities that generally are performed outside the context of a face-to-face, in-person visit, most often by the billing practitioner's clinical staff on behalf of patients with complex health care needs, including transitional care management in the CY 2013 PFS final rule (77 FR 68979); non-complex and complex chronic care management (CCM) in the CY 2015, 2017, and 2019 PFS final rules (78 FR 74414, 83 FR 58577, and 81 FR 80244); and principal care management (PCM) in the CY 2020 PFS final rule (84 FR 62962). The CCM and PCM code families now include five sets of codes which are reported monthly on a timed basis, each set with a base code of 20 to 60 minutes and an add-on code for each additional 30 minutes. The code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner (NPP) is used to meet time thresholds for billing. We remind commenters of these services which are available for care management and coordination, to support beneficiaries with a variety of complex health needs. Furthermore, we will continue to engage with interested parties on this topic and are interested in information that could assist us in estimating physician intraservice time for covered services.

Comment: Several commenters indicated that despite our stated intention to exclude time-based services from the efficiency adjustment, we included several time-based services including physical medicine and rehabilitation services and remote therapeutic monitoring (RTM) on the list of services which we proposed to apply this adjustment.

A commenter stated that telehealth services are excluded from the adjustment, but some telehealth codes are on the impacted efficiency adjustment list.

Additionally, several commenters stated that diagnostic, prophylactic, or therapeutic intravenous infusions, such as chemotherapy, should not be subject to the efficiency adjustment, as the infusion rates are recommended on the required FDA labeling, and therefore cannot be made more efficient, or delivered at a faster rate.

Several commenters requested exclusions of:

- Certain specialties, non-time-based codes, and/or services (for example, specialties with workforce shortages, annual wellness visits (AWVs), bariatric surgery codes, cataract codes, etc.).
- Services where efficiencies would compromise patient safety.
- Codes for services valued through crosswalk rather than RUC surveys.
- Software-based services, such as Artificial Intelligence-enabled Coronary Plaque Analysis (AI-CPA) and Fractional Flow Reserve derived from Computed Tomography, as they do not yield efficiency gains with increased use.

Response: We appreciate the commenters' diligence in reviewing the list of services to which we proposed to apply the efficiency adjustment. We agree with the commenters that time-based services and services on the CMS telehealth list should be included in the list of codes exempt from the efficiency adjustment list. We have removed the time-based physical medicine and rehabilitation services and RTM services and services on the CMS telehealth list from the list of codes to which the efficiency adjustment will apply. Additionally, we appreciate the information provided by the commenters with regard to FDA labeling for diagnostic, prophylactic, or therapeutic intravenous infusions. We are removing time-based, drug administration codes from the list of codes to which the efficiency adjustment will apply in CY 2026. We continue to believe that applying the efficiency adjustment to non-time-based services more broadly, instead of applying it only to certain services, will help to improve the overall accuracy of our valuation of these services under the +PFS. Given our commitment to refining the efficiency adjustment over time, we look forward to continued engagement with the public on future rulemaking for these services. We welcome any empirical data regarding physician intraservice work time for PFS services

that commenters are able to submit to us. Interested parties can submit their request as part of the Potentially Misvalued Codes initiative, as described in section II.C. of this final rule.

Comment: A commenter requested a hold harness policy for rural and safety net providers.

Response: We appreciate the commenter's feedback and may consider this for future rulemaking.

Comment: Several commenters requested that CMS conduct a more targeted review of specific codes rather than applying a broad application. Some commenters requested that CMS apply the efficiency adjustment to only a subset of codes, that is, older codes that have not been revalued for 17-25 years, exempting codes that take less time to perform, focusing on high volume codes, etc. Several commenters supported the efficiency adjustment, and some of these commenters urge careful consideration of its implementation to avoid unintended consequences. Several commenters recommend delaying implementation to conduct specialty specific reviews, or to phase in implementation (that is, over 3 years) to give organizations time to adjust to changes in revenue. Some commenters stated CMS should use a shorter lookback period, while other commenters stated CMS should use a longer lookback period, such as a 10 year lookback period.

Response: We appreciate the commenter's feedback on the efficiency adjustment proposal. As stated in proposed rule, the efficiency adjustment proposal reflects a conservative approach based on studies of overvaluation, which is why we are using a conservative 5-year lookback period. While we acknowledge the suggestions to delay or phase in implementation and to conduct specialty-specific reviews, we continue to believe the proposal is an appropriate balance between timely policy implementation and the need for future refinement. We are committed to continue engaging with the public and will continue to consider public feedback on the efficiency adjustment policy, as we may need to make refinements and would address through future rulemaking accordingly.

Comment: Many commenters also provided recommendations for CMS to consider assisting with more accurate valuation of codes including:

- Bundling related services into broader payment packages, stating that CMS could decrease the administrative burden associated with frequent code-specific revaluations, allowing greater focus and in turn accuracy. Consolidating codes in this manner would streamline data collection, code review, and

payment adjustments, and better align the PFS with established practices in other Medicare payment systems.

- Establishing a Technical Advisory Panel to discuss and advise on service packages, service valuation including the appropriate collection and use of empirical data, code level estimates of physician intraservice time, cadence for updates, and potential efficiency adjustments while considering the potential impact on physicians, beneficiaries, and the Trust Fund.
- Consider implementing a modifier or HCPCS G-code for surgical complexity so that surgeons will be able to identify the cases that are more complex, which would more directly and appropriately address CMS' interest in isolating the services that are truly more efficient.

Also, the commenters recommended CMS work with medical professionals to develop time and motion studies for high volume procedures to determine if there are or have been any efficiency gains over time. The commenters believe empirical data is needed to support this policy, such as data points that may be captured by analyzing EHR data.

Response: We appreciate the commenters for their feedback and may consider these suggestions for future rulemaking.

Comment: Several commenters stated that CMS should not make corresponding adjustments to direct PE input for clinical labor or equipment because these costs have only increased. They also suggest that CMS consult with interested parties and seek input from the RUC.

A few commenters recommended making corresponding updates to the inputs for clinical labor and equipment costs and to factor all those changes into CMS' indirect PE methodology, where appropriate. The commenters stated that not making these changes creates a distortion in which CMS is not fully accounting for the efficiencies garnered over time as technology advances, workflows improve, and expertise develops. The commenters continued to state that procedures that become more efficient, for example, also reduce clinical labor time and costs and equipment costs (for example, since the equipment is being used for less time).

Response: We appreciate the comments submitted by the public and may consider these suggestions for possible future rulemaking.

Comment: Several commenters stated that they were unable to replicate the productivity adjustments that are used to derive the proposed efficiency adjustment. They state that these productivity adjustments for 2022 to 2026 are not listed in either of the CMS online tables related to the MEI or in information available from the U.S. Bureau of Labor Statistics (BLS). A few commenters requested that CMS supplement the values posted in Table A-E1 of the CY 2026 PFS proposed rule (90 FR 32593) with a brief narrative describing the calculation methodology, any year-over-year rounding conventions, and the precise source data (for example, Bureau of Labor Statistics series) used for each input in a separate file to be posted to the CMS webpage.

Response: Total factor productivity (TFP), as measured by the U.S. Bureau of Labor Statistics (BLS), captures the portion of economic growth that cannot be explained solely by increases in labor and capital inputs. Instead, it reflects improvements in efficiency, technology, organizational practices, and other factors that enhance how inputs are combined to produce output. Unlike labor productivity, which only looks at output per hour worked, TFP accounts for multiple inputs, including labor (adjusted for composition), capital, and intermediate goods, using cost-share weights to build combined input indexes. Because it represents a residual, TFP is sensitive to measurement quality but is widely viewed as an indicator of innovation and long-term potential growth.

BLS TFP data are revised on a regular basis to incorporate updated source data, methodological improvements, and benchmarking adjustments. Because TFP relies on inputs from other agencies, such as Gross Domestic Product and capital data from the Bureau of Economic Analysis and labor data from Census surveys and the Current Population Survey, revisions to those underlying sources flow into BLS TFP estimates. In addition, changes in methodology, such as the 2022 update to labor composition measurement, can lead to historical revisions. Typically, BLS issues annual revisions for TFP in the private business, private nonfarm business, and manufacturing sectors, as well as for detailed industries to reflect any methodological changes and to incorporate more recent data.

BLS typically publishes TFP data on an annual schedule, with an initial preliminary release followed by revised (final) estimates once more complete source data is available.

As stated in the CY 2026 PFS proposed rule (90 FR 32593), the productivity adjustments used in the proposed efficiency adjustment are based on the BLS TFP data for the private nonfarm business

sector. Preliminary TFP estimates for the private nonfarm business sector are typically released in March for the prior year. For example, 2024 preliminary TFP data were released in March 2025. These estimates rely on the most up to date but still incomplete data from the Bureau of Economic Analysis (BEA), Census, and other sources. Final (revised) TFP estimates are usually incorporated in the fall release cycle (often around November to December), when more complete national accounts and input data are available. At this point, BLS re-estimates the TFP measures for the most recent year and may also revise prior years.

Table A-E3 lists the BLS TFP release dates for the years 2020 to 2024 for both the preliminary publication and the later revision ("final") date when BLS issued a formal revision.

TABLE A-E3: LISTS THE BLS TFP RELEASE DATES FOR THE YEARS 2020 TO 2024 FOR BOTH THE PRELIMINARY PUBLICATION

TFP Data year	Preliminary TFP release	"Final" / revision Publication	PFS Update Year (CY)
2020	Mar 23, 2021 (MFP Trends — 2020).	Nov 18, 2021	2022
2021	Mar 24, 2022 (TFP — 2021).	Nov 18, 2022	2023
2022	Mar 23, 2023 (TFP — 2022).	Nov 21, 2023	2024
2023	Mar 21, 2024 (TFP — 2023).	Dec 4, 2024	2025
2024	Mar 21, 2025 (TFP — 2024).	TBD (Nov. or Dec. 2025)	2026

The preliminary TFP estimates do not remain as a separate, permanent data set. When BLS releases revised (or "final") estimates later in the year, the new numbers overwrite the preliminary figures in the public data tables. The archived TFP data can be obtained from the archived TFP news releases at https://www.bls.gov/bls/news-release/home.htm#tfp.

To determine the productivity adjustment, we use the annual index levels for total factor productivity from 1987 to the latest year of data published by BLS at the three decimal level of precision. We then calculate the 10-year moving average of the annual index levels to derive the 10-year average TFP index level, unrounded. Next, we calculate the growth rate of the current year to the prior year of the 10-year average index levels to derive the 10-year moving average growth. Finally, this value is rounded to 1 decimal place to arrive at the final applicable productivity adjustment. Questions related to the methodology for how TFP is calculated should be directed to the Bureau of Labor Statistics – Office of Productivity and Technology (OPT), https://www.bls.gov/productivity.

We acknowledge commenters' concerns that the MEI update and productivity adjustment have not been published separately in the recent CY PFS regulations on a consistent basis since it is not used to calculate PFS payment rates, with the exception of the telehealth originating site facility fee; however, the relevant information is available by reference to the FQHC market basket update, which is based on the latest historical data at the time of the publication of the final rule. The "Actual Regulation Market Basket Updates (ZIP)" link in the downloads section of the following cms.gov webpage contains a spreadsheet that details the productivity adjustment applied for each FQHC market basket update: https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data. The productivity adjustment in the FQHC market basket for the corresponding period would match that of the MEI and is consistent with the information provided in the proposed rule.

We highlight that the productivity adjustment applicable to the CY 2026 MEI and FQHC market basket updates is finalized to be 0.8 percentage point, the same as was proposed. The productivity adjustment corresponding to the payment update for CY 2026 incorporates the Bureau of Labor Statistics' total factor productivity estimates through 2024, published on March 21, 2025. This adjustment is determined by calculating the 10-year moving average of changes in annual economy-wide, private nonfarm business total factor productivity.

Table A-E4 presents the efficiency adjustment of 2.5 percent, which is derived from the cumulative productivity adjustments finalized in each PFS final rule from CY 2022 through CY 2026. Additionally, we provide a comparison of the estimated productivity adjustment based on the latest revised TFP data available from BLS at the time of this CY 2026 PFS final rule.

TABLE A-E4: Productivity Adjustment Data CY 2022 through CY 2026

PFS Payment Year	Published Productivity Adjustment	Latest Productivity Adjustment based on revised BLS TFP data
CY 2022	0.2%	0.4%
CY 2023	0.5%	0.9%
CY 2024	0.4%	0.7%
CY 2025	0.6%	0.8%
CY 2026	0.8%	0.8%
Efficiency Adjustment	2.5%	3.6%

While there are updated percentages based on revised BLS TFP data at the time of drafting this final rule, as indicated in Table A-E4, we note that our proposed approach was designed to be conservative in nature, as we are concerned about making too many changes at once to the current methodology. Therefore, as we discuss in the summary for this section, we are finalizing the proposed efficiency adjustment of 2.5 percent for CY 2026.

Comment: Several commenters stated that it is unreasonable for CMS to apply the efficiency adjustment, essentially a productivity adjustment, to reduce PFS payments when there is no corresponding market basket or inflationary adjustment to increase PFS payments annually. The commenters observed that, unlike other Medicare FFS payment systems where a market basket percentage increase is calculated and then reduced by a productivity adjustment to determine the final payment rate update, CMS is proposing to apply a type of productivity adjustment to decrease payment for the PFS without the associated yearly payment increase of a market basket. The commenters suggested that CMS should work with Congress to make sure there is a permanent change to the PFS to ensure that there is a mechanism to account for annual input price inflation, such as the MEI update. Several commenters requested that CMS provide additional clarification surrounding why the agency believes that this measure of overall productivity growth across the economy is an adequate proxy for service-level efficiency gains within the Medicare program and stated their belief that it is unreasonable to extrapolate changes in physician productivity from estimates of nonfarm business productivity across the entire economy. Additionally, a commenter supported the use of the MEI productivity adjustment as a basis for the efficiency adjustment, stating that it is a good approximation of physician-specific multifactor productivity.

Response: We appreciate the comments regarding using the MEI productivity adjustment to calculate the efficiency adjustment. We acknowledge that, unlike other Medicare payment systems where annual payment updates are based on a market basket increase that is then adjusted for productivity, the PFS does not include an automatic mechanism to account for inflationary input cost growth.

However, we continue to believe that the productivity adjustments used in the proposed efficiency adjustment, based on the BLS TFP data for the private nonfarm business sector, is a reasonable and appropriate proxy for productivity improvements that can be expected over time in the provision of

physician services. While we recognize that the data reflects productivity growth in the broader nonfarm business sector, it is the widely accepted and consistently measured estimate of economy-wide productivity gains used to adjust the FFS annual market basket updates as required by section 3401 of the Affordable Care Act (ACA), These legislatively mandated payment adjustments have been used across most FFS Medicare payment systems since 2012.

We appreciate commenters' suggestions that CMS work with Congress to explore statutory changes that would allow for a more comprehensive update framework under the PFS, including mechanisms to account for annual input price inflation. While CMS does not have the authority to make such changes unilaterally, we understand the importance of these concerns and will continue to consider commenter's suggestions as we continue to make refinements to this policy through future rulemaking.

We also note that at a commenter supported the use of the MEI productivity adjustment, stating that it represents a reasonable approximation of physician-specific multifactor productivity. We continue to believe that the MEI productivity adjustment provides a useful and analytically supported approach to account for efficiency gains and ensure consistency with broader Medicare payment policy. We continue to welcome, review and consider the public's feedback on this issue and will evaluate whether refinements or alternative approaches may be appropriate in future rulemaking.

Comment: We received several comments regarding the cadence of the efficiency adjustment proposal. Several commenters also requested that CMS clarify its decision to continually apply the efficiency adjustment every 3 years. A few commenters stated that anything more than a one-time adjustment is unwarranted. Other commenters described that efficiencies cannot continue to be gained year-over-year and that at some point, there is a maximum efficiency that can be realized, and going beyond that point will compromise patient care. A commenter stated that the efficiency adjustment is different from the GPCI and MP updates, in contrast to those updates, which have occurred every 3 years for decades with finite and consistent impact on affected services, the efficiency adjustment has the potential to be substantially disruptive to the fee schedule every year it is implemented. The commenter recommended CMS to defer subsequent efficiency adjustments until the impact on Medicare patient care can be appropriately evaluated to ensure that it is not harmful. A commenter stated that technological adoption is rarely linear and believes 3 years is insufficient to determine that innovation and efficiency

have been embedded across an entire procedure or service. The commenter recommended CMS extend the adjustment period beyond 3 years to provide adequate time to assess the impacts of innovative technologies on their workflows and care delivery. Another commenter stated implementing a consistent 2.5 percent reduction every 3 years indefinitely risks causing ongoing cuts to payments for certain services, without clear evidence that further efficiencies are actually achievable. Another commenter stated that CMS did not specify an endpoint for the efficiency reduction. The commenter continued to state that as proposed, CMS would, theoretically, continue to apply the efficiency adjustment until such time that the intraservice time is zero.

Response: We appreciate the commenters for their thoughtful input. We acknowledge the concern that efficiencies may not accrue indefinitely and that overly repeated application of the efficiency adjustment could have cumulative effects over time. As such, we will continue to monitor the impact of the efficiency adjustment. While we proposed a 3-year cadence, we may revisit the frequency and consider establishing a sunset provision or other refinements in future rulemaking.

After consideration of public comments, for CY 2026 we are finalizing to establish an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services, with refinements. We will apply the efficiency adjustment to the intraservice portion of physician time and work RVUs every 3 years. To calculate the efficiency adjustment, we are finalizing the use of the MEI productivity adjustment over a 5-year look back period from CY 2022 to CY 2026. We note, as displayed in Table A-E4, using more recent historical data from the BLS yielded an efficiency adjustment of 3.6 percent. As we discussed in the CY 2026 PFS proposed rule (90 FR xxx), our approach in applying an efficiency adjustment is to take into account changes in medical practice and to better reflect resources involved, and it is designed to be conservative in nature, as we are concerned about making too many changes at once to the current methodology. Therefore, we are finalizing the proposed efficiency adjustment of 2.5 percent. We are exempting additional codes, specifically time-based codes, services on the CMS telehealth list, and new codes for CY 2026, as reflected in the Codes Subject to Efficiency Adjustment file. This file can be found in the public use files for CY 2026; the file is available on the CMS website under downloads for the CY 2026 PFS final rule at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

3. Methodology for the Direct PE Inputs to Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or non-facility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table A-E13 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this final rule, we also note that

many of the refinements listed in Table A-E13 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2026 are displayed in the CY 2026 direct PE input files, available on the CMS website under the downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the CY 2026 PE RVUs as displayed in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment

items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, in that rule we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the "PE worksheets." For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items that are not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2026 we received invoices for several new supply and equipment items. Tables A-E13 and A-E14 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables A-E13 and A-E14 also include the number of invoices received and the number of non-facility allowed services for procedures that use these equipment items. We provide the non-facility allowed services so that interested parties will note the impact the particular

price may have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we may identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we may use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2026 are available on the

CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we referred readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on February 8, 2006) amended section 1848(b)(4) of the Act to require that, for imaging services, if— (i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under section 1833(t)(2)(D) of the Act, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor under the PFS, for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography." For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the "OPPS cap"), we referred readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2026, we identified new and revised codes to determine which services meet the definition of "imaging services" as defined at section 1848(b)(4)(B) of the Act for purposes of this cap. Beginning for CY 2026, we proposed to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0598T (*Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound pathogens and measure wound size, per session; first anatomic site (that is,, lower extremity, right leg*), 0599T (*Real-time fluorescence wound imaging with clinical*

darkness, to identify location of bacterial wound pathogens and measure wound size, per session; each additional anatomic site (that is,, upper extremity, left leg) (List separately in addition to code for primary procedure)), 0944T (*3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation*), 0946T (*Orthopedic implant movement analysis using paired computed tomography (CT) examination of the target structure, including data acquisition, data preparation and transmission, interpretation and report (including CT scan of the joint or extremity performed with paired views)*), 0961T (*Shortwave infrared radiation imaging, surgical pathology specimen, to assist gross examination for lymph node localization in fibroadipose tissue, per specimen (List separately in addition to code for primary procedure)*), 0972T (*Assistive algorithmic classification of burn healing (ie, healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report*), 0984T (*Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)*), 0985T (*Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)*), 0986T (*Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)*), 0987T (*Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)*), 70471 (Computed tomographic *angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing*), 70472 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s),* including image postprocessing *performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)*), 70473

(*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy*), and 77X09 (*Surface radiation therapy; superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to the code for primary procedure)*). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

We appreciate commenters' feedback regarding CPT codes 92227 (*Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral),* 92228 (*Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral*), and 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral*), and may consider adding this code to the OPPS cap list for future rulemaking, however as we did not make a specific proposal regarding this service, we consider these comments out of scope for this rule but we appreciate the additional information and may consider it for future rulemaking. We did not receive public comments on the proposed additions to the OPPS cap list for CY 2026. We are finalizing the addition of the services listed above to the list of codes to which the OPPS cap applies, as proposed.

4. Valuation of Specific Codes for CY 2026

(1) Tympanostomy (CPT code 0583T)

In the CY 2025 PFS final rule (89 FR 97745 through 97746), we reviewed Category III CPT code 0583T (*Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia)* as potentially misvalued. We considered whether to establish national payment for CPT code 0583T, which is used to report tympanostomy using the TULA system, or whether to create a device-agnostic G-code which could be used to report tympanostomies using the TULA or other devices. We stated that CPT code 69433 (*Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia*) may serve as a sufficient base code, adequately describing most of the surgeon's work and facility resources. In response to comments supporting the latter approach, we established separate payment for HCPCS code G0561 (*Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral*

(List separately in addition to 69433) (Do not use in conjunction with 0583T)) to be billed with CPT code 69433 in order to describe the additional resource costs associated with using the innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories and finalized contractor pricing for CY 2025.

We have received input from interested parties expressing gratitude for the creation of HCPCS code G0561 but also continuing to request that CMS establish national pricing for CPT code 0583T. In response, we sought comments on whether to nationally price both codes, and what inputs for physician work, time, and direct practice expense would most accurately capture the resource costs associated with performing both procedures. For example, in response to a similar request for comment in CY 2025 PFS rulemaking, commenters recommended a direct crosswalk to the values associated with CPT code 31295 (*Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa*) which they stated was similar to CPT code 0583T with respect to the intensity and invasiveness of the procedure, preparation time for the procedure, and total time to complete the surgery. We sought comments on whether interested parties continue to believe CPT code 31295 would be an accurate comparison or whether there are other services that CMS should consider.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The RUC indicated that CPT codes 0583T, 69433, and HCPCS code G0561 will be placed on the next level of interest for review.

Response: We acknowledge and appreciate the AMA for the RUC's placement of CPT code 0583T, 69433, and HCPCS code G0561 on their next level of interest for review list and look forward to their input, as well as input from the initial submitters of CPT code 0583T and all other interested parties.

Comment: Many commenters supported national pricing for CPT code 0583T. These commenters stated that national pricing will improve patient access to the procedure and align with time and resources involved, ensuring accurate payment for practitioners performing this procedure in the office setting. Commenters also supported a crosswalk to CPT code 31295 to describe the resources associated with the innovative tympanostomy tube delivery devices and/or systems described by CPT code 0583T, stating

that the physician work, time, and direct PE inputs reflected in CPT code 31295 are similar to those of 0583T.

Response: We appreciate the commenters for their feedback.

Comment: A few commenters did not support national pricing for HCPCS code G0561. These commenters recommended waiting until more data and clinical experience become available to support national pricing. Other commenters supported national pricing for HCPCS code G0561 and requested different payment rates for CPT code 0583T and HCPCS code G0561.

Response: We agree with commenters that it may be beneficial to collect more data on the use of HCPCS code G0561 prior to proposing national pricing. Therefore, we are finalizing to maintain contractor pricing for HCPCS code G0561. Regarding pricing for CPT code 0583T, we are persuaded by the comments that stated that the physician work, time, and direct PE inputs reflected in CPT code 31295 are similar to those of 0583T, therefore, we are finalizing a crosswalk to the input values associated with CPT code 31295 for CPT code 0583T for CY 2026.

(2) Temporary Female Intraurethral Valve-Pump (CPT codes 0596T and 0597T)

For the CY 2025 PFS final rule (89 FR 97710), we reviewed CPT codes 0596T (*Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, including urethral measurement*) and 0597T (*Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, replacement*) as potentially misvalued. We added pricing for 3 new supplies related to these services: (1) inFlow Measuring Device, (2) inflow Valve Pump Device, and (3) inFlow Activator Kit. The RUC reviewed and surveyed these codes as potentially misvalued for the January 2025 meeting and stated that they would flag for the RAW in 3 years.

We proposed the RUC-recommended work RVU of 2.43 for CPT code 0596T and the RUC-recommended work RVU of 1.05 for CPT code 0597T.

We proposed the RUC-recommended direct PE inputs for both CPT codes without refinement.

We did not receive any public comments on this policy, and therefore, we are finalizing as proposed.

(3) Skin Cell Suspension Autograft

Comment: We received comments that requested CMS clarify policies related to CPT codes 15011, 15012, 15013, 15014, 15015, 15016, 15017, and 15018. The commenters recommended that CMS establish national pricing for these services.

Response: At this time, our concerns expressed in the CY 2025 PFS final rule (89 FR 97774 through 97776) have not been resolved regarding these services. We continue to have concerns about the service times, segmentation of the coding, and billing patterns of the add-on codes based on the vignettes. We continue to believe contractor pricing is appropriate for these services and look forward to reviewing these codes again after reconsideration of the coding structure and re-survey is complete. Additionally, we did not propose to nationally price these services in the CY 2026 PFS proposed rule (90 FR 32593), so those changes cannot be finalized. We encourage interested parties to work with the MACs to develop the crosswalks for these services while they continue to be contractor priced.

(4) Limb Lengthening-Shortening – Femur (CPT codes 27465, 27466, 27468, and 27458)

The CPT Editorial Panel created a new Category I code, CPT code 27458 *(Osteotomy(ies), femur, unilateral, with insertion of an externally controlled intramedullary lengthening device, including iliotibial band release when performed, imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device)* in May 2024. This code describes femur lengthening using the insertion of an externally controlled intramedullary lengthening device, including imaging. CPT code 27458 and the other codes within this code family, including CPT codes 27465 *(Osteoplasty, femur; shortening (excluding 64876)*, 27466 *(Osteoplasty, femur; lengthening)*, and 27468 *(Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer)*, were surveyed during the September 2024 RUC Meeting.

We proposed the RUC-recommended work RVUs of 26.65, 21.13, and 22.65 for CPT codes 27458, 27465, and 27466, respectively. We also proposed the direct PE inputs for CPT codes 27458, 27465, and 27466 without refinement.

However, for CPT code 27468, we disagreed with the RUC's recommendation to contractor price this code. We believe CPT code 27468 is valued appropriately and should not be paid under contractor pricing based on the results of ten surveys. We instead proposed to maintain the current work RVU and direct PE inputs for CPT code 27468 for CY 2026.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter, the AMA, stated at the May 2025 CPT Editorial Panel meeting, CPT code 27468 was deleted for CY 2026 due to the specialty request due to low volume. This was reflected in the CY 2026 RUC resource files submitted to CMS in May 2025. Therefore, the RUC recommended the deletion of CPT code 27468 from Addendum B as the code will not exist in 2026. The same commenter was in support of our proposal of the RUC recommended values for CPT codes 27458, 27465, and 27466.

Response: We appreciate the commenter for their feedback and for the additional information regarding CPT 27468.

After consideration of public comments, we are finalizing our proposed values for CPT codes 27458, 27465, and 27466. For CPT code 27468, we are finalizing the deletion of this code as it will no longer exist in 2026.

(5) Limb Lengthening-Shortening – Tibia (CPT codes 27715 and 27713)

The CPT Editorial Panel created a new Category I code, CPT code 27713, *(Osteotomy(ies), tibia, including fibula when performed, unilateral, with insertion of an externally controlled intramedullary lengthening device, including imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device)* in May 2024. This code describes tibia lengthening using the insertion of an externally controlled intramedullary lengthening device, including imaging. CPT codes 27713 and 27715 (*Osteoplasty, tibia and fibula, lengthening or shortening)* were surveyed for the September 2024 RUC Meeting.

We proposed the RUC-recommended work RVU of 28.00 for CPT code 27713 and the work RVU of 22.50 for CPT 27715. We also proposed the direct PE inputs for CPT codes 27713 and 27715 without refinement.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed.

(6) Arthrodesis Great Toe (CPT codes 28750 and 28755)

At the April 2024 Relativity Assessment Workgroup (RAW), the RAW identified CPT code 28750 (*Arthrodesis, great toe; metatarsophalangeal joint*) on the "different performing specialty from survey screen," where the top specialty performing over 50 percent of the Medicare claims did not survey the service or the top two specialties did not survey the service. The RAW noted that when this service was last valued in 1995, podiatry, which now performs over half of the volume for this service, was not involved in the survey. CPT code 28755 (*Arthrodesis, great toe; interphalangeal joint*) which was valued by the Harvard Studies and never surveyed by the RUC, was added as part of the code family. CPT codes 28750 and 28755, were surveyed at the January 2025 AMA RUC meeting.

We proposed the RUC-recommended work RVU of 8.75 for CPT code 28750.

We disagreed with the RUC-recommended work RVU of 7.50 for CPT code 28755 and we instead proposed a work RVU of 6.76. The RUC-recommended valuation would place it above the median range when compared to other 90-day global codes with similar work times and the current time and work values. We proposed a work RVU of 6.76 for CPT code 28755 based on a direct crosswalk to CPT code 28122 (*Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (for example, osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*). CPT code 28122 shares the same intraservice work time of 45 minutes as compared with CPT code 28755, it has a very similar total time (230 minutes as compared with 234 minutes), and both of these codes also contain four postoperative office visits in their global periods. We are supporting this proposed work RVU of 6.76 with the total time ratio for CPT code 28755, which calculates at a work RVU of 6.64 (the total time is increasing from 172 minutes to 234 minutes for an increase of 36 percent, which results in a work RVU of 6.64 when multiplied with the current work RVU of 4.88 for CPT code 28755). Our proposed work RVU of 6.76 is further supported by a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 26785 (*Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed, single*) at a work RVU of 6.60 and an upper bracket of CPT code 56620 (*Vulvectomy simple; partial*) at an RVU of 7.53.

We proposed the RUC-recommended direct PE inputs for all of the codes in this family.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally agreed with CMS' proposal of the RUC-recommended work and direct PE inputs for CPT code 28750.

Response: We appreciate the commenters for taking the time to submit comments. After reviewing the comments, we are finalizing the proposed work RVU and direct PE inputs for CPT code 28750.

Comment: A few commenters disagreed with CMS' proposal to lower the work RVU to 6.64 for CPT code 28755. The commenters stated that the Harvard study under which CPT code 28755 was previously valued did not include podiatrists and was reviewed by only nine general orthopedic surgeons. Additionally, the Harvard study did not survey pre- or post-service work or time and instead estimated time based on an algorithm. Additionally, no positioning time was assigned, and post-operative work was underestimated based on this methodology.

Commenters disagreed with the selected crosswalk code, CPT code 28122, stating that the code under review is more intense and requires more work than the selected crosswalk code and has more time, work, effort, and risk involved. Commenters suggested CMS to finalize the RUC-recommended work RVU of 7.50 for CPT code 28755.

Response: We appreciate the commenters for their suggestions. We agree with the case made by commenters that CPT code 28755 is more difficult to perform than CPT code 28122 because CPT code 28755 involves smaller bones. In addition, the RUC-recommended value is supported by a search of similarly timed codes, with the value of 7.50 landing between the mid and upper third of values.

After consideration of public comments, we are not finalizing our proposed work RVU of 6.76 for CPT code 28755 and we are instead finalizing the RUC-recommended work RVU of 7.50. We are finalizing the RUC-recommended direct PE inputs for all of the codes in this family.

(7) Closure Left Atrial Appendage with Endocardial Implant (CPT code 33340)

The Relativity Assessment Workgroup (RAW) reviewed CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*) in 2023 as part of the new technology/service screen. Around that same time, specialty societies asserted that this service was

undergoing rapid change. Therefore, the RAW recommended specialty societies conduct a survey for the April 2024 RUC meeting.

We proposed the RUC-recommended work RVU of 10.25 for CPT code 33340. We also proposed the RUC-recommended direct PE inputs for CPT code 33340 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed the CMS proposal of the RUC-recommended work RVU of 10.25 for CPT code 33340 because these commenters believe that the decrease in work RVU from 14.00 to 10.25 was too drastic and could impact beneficiaries' access to these services. A few commenters also disagreed with the comparison to CPT code 49614, stating that it was an inappropriate choice for a valuation crosswalk.

Response: While we understand commenters' concerns, we believe that the RUC-recommended work RVU and direct PE inputs for CPT code of 33340 are appropriate choices for valuation. When CPT code 33340 was surveyed, the intraservice time decreased from 90 minutes to 70 minutes (about 28 percent) while the total time decreased from 183 minutes to 165 minutes (about 11 percent). Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We believe that CPT code 49614 is an accurate crosswalk for work valuation as it has comparable intraservice time to CPT code 33340 (75 minutes against 70 minutes) and the two codes share the identical total time of 165 minutes.

After consideration of the public comments, we are finalizing our proposed work RVUs and direct PE inputs for CPT code 33340.

(8) Thoracic Branch Endograft Services (CPT codes 33880, 33881, 33883, 33886, 33882, and 35602)

At the September 2024 CPT Editorial Panel meeting, CPT approved endovascular repair of thoracic aortic aneurysms (TEVAR) coding changes. CPT deleted three codes describing the procedure and replaced them with two new codes and four revised codes in the TEVAR family. These revisions update the TEVAR code family to more accurately describe the current practice and current coding

standards. The new codes are CPT code 33882 (*Endovascular repair of the thoracic aorta by deployment of a branched endograft multipiece system involving an aorto-aortic tube device with a fenestration for the left subclavian artery stentgraft(s) and all aortic tube endograft extension(s) placed from the level of the left common carotid artery to the celiac artery, including preprocedure sizing and device selection, all target zone angioplasty, all nonselective catheterization(s) and left subclavian artery selective catheterization(s), all associated radiological supervision and interpretation*), CPT code 35602 (*Bypass graft, with other than vein; carotid-contralateral carotid*), CPT code 33880 (*Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation*), CPT code 33881 (*by deployment of an aorto-aortic tube endograft not involving coverage of the left subclavian artery origin and all endograft extension(s) placed from the level of the left subclavian carotid artery to the celiac artery*), CPT code 33883 (*Proximal extension prosthesis(s) not involving coverage of the left subclavian artery origin, delayed placement after endovascular repair of the thoracic aorta, including preprocedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed*), and CPT code 33886 (*Distal extension prosthesis(s) from the level of the left subclavian artery to the celiac artery, delayed placement after endovascular repair of descending thoracic aorta, including preprocedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation*). The new codes in this code family were surveyed at the January 2025 AMA RUC meeting.

The RUC surveyed this code family and there were overall decreases in the work times. The RUC-recommended work RVUs do not appear to fully account for these decreases. Although we do not believe that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, decreases in the surveyed work time should typically be reflected in decreases to the work RVU.

We reviewed the RUC recommendations and found them to be high, relative to other codes with the same or similar times. Based on a search of similarly timed codes in the RUC database, the RUC-recommended values exceed the work RVUs for five of the six codes.

We disagree with the RUC recommended work RVU of 30.00 for CPT code 33880 and instead we proposed a work RVU of 27.00. This valuation was higher than nearly all of the other 90-day global codes with similar time values. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with an intraservice time of 120 minutes and similar total time around 546 minutes. We instead proposed a direct crosswalk to CPT code 32672 (*Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed*) at the previously mentioned work RVU of 27.00. CPT code 32672 shares the same intraservice work time of 120 minutes as compared with CPT code 33880, it has a similar total time (567 minutes as compared with 546 minutes), and both of these codes each have two postoperative office visits in their global periods. We are supporting this proposed work RVU of 27.00 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 43820 (*Gastrojejunostomy; without vagotomy*) at a work RVU of 22.53 and an upper bracket of CPT code 34702 (*Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (for example, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)*) with a work RVU of 36.00.

We disagree with the RUC recommended work RVU of 26.75 for CPT code 33881 and we instead proposed a work RVU of 22.53. The RUC's recommended work RVUs do not match the surveyed drops in work time (from 200 minutes to 110 minutes for CPT code 33881) and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 43820 has a slightly higher intraservice work time of 120 minutes as compared with CPT code 33881 which has 110 minutes, it has a very similar total time (545 minutes as compared with 506 minutes), and

three postoperative office visits as compared to CPT code 33881 which has two postoperative office visits in the global period. We are supporting this proposed work RVU of 22.53 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 34707 at a work RVU of 22.28 and an upper bracket of CPT code 43880 at an RVU of 27.18.

We disagree with the RUC recommended work RVU of 39.00 for CPT code 33882 and we instead proposed a work RVU of 35.00. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 180 minutes and similar total time around 621 minutes. We proposed a work RVU of 35.00 for CPT code 33882 based on a direct crosswalk to CPT code 33390 (*Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; simple (ie, valvotomy, debridement, debulking, and/or simple commissural resuspension)*). There were several recently reviewed codes in the RUC database search that have the exact same intraservice time with higher total times and a lower work RVU. CPT code 33390 shares the same intraservice work time of 180 minutes as compared with CPT code 33880, it has a very similar total time (621 minutes as compared with 622 minutes), and both of these codes also contain two postoperative office visits in their global periods. We are supporting this proposed work RVU with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 33647 (*Repair of atrial septal defect and ventricular septal defect, with direct or patch closure*) at a work RVU of 33.00 and an upper bracket of CPT code 35216 (*Repair blood vessel, direct; intrathoracic, without bypass*) at an RVU of 35.00.

We disagree with the RUC recommended work RVU of 24.25 for CPT code 33883 and we instead proposed a work RVU of 19.91. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 90 minutes and similar total time around 486 minutes. We proposed a work RVU of 19.91 for CPT code 33883 based on a direct crosswalk to CPT code 44320 (*Colostomy or skin level cecostomy*).

The RUC-recommended work RVUs do not match the surveyed drops in work time (from 120 minutes to 90 minutes) for CPT code 33883 and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 44320 shares the same intraservice work time of 90 minutes as compared with CPT code 33883, it has a slightly higher total time (507 minutes as compared with 486 minutes), and three postoperative office visits as compared to two post

operative office visits for CPT code 33883 in the global period. We are supporting this proposed work RVU of 19.91 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 33267 (*Exclusion of left atrial appendage, open, any method (for example, excision, isolation via stapling, oversewing, ligation, plication, clip)*) at a work RVU of 18.50 and an upper bracket of CPT code 43611 (*Excision, local; malignant tumor of stomach*) at an RVU of 20.38.

We disagree with the RUC recommended work RVU of 23.50 for CPT code 33886 and we instead proposed a work RVU of 19.91. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 90 minutes and similar total time around 486 minutes. We proposed a work RVU of 19.91 for CPT code 33886 based on a direct crosswalk to CPT code 44320. The RUC-recommended work RVUs do not match the surveyed drops in work time (from 100 minutes to 90 minutes) for CPT code 33886 and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 44320 shares the same intraservice work time of 90 minutes as compared with CPT codes 33886, it has a slightly higher total time (507 minutes as compared with 486 minutes), and three postoperative office visits as compared to two post operative office visits for CPT code 33886 in the global period. We are supporting this proposed work RVU of 19.91 with a pair of other 90-day global codes with similar work time values, with a lower bracket of CPT code 33267 at a work RVU of 18.50 and an upper bracket of CPT code 43611 at an RVU of 20.38.

We disagree with the RUC recommended work RVU of 27.40 for CPT code 35602and we instead proposed a work RVU of 23.53. We found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 150 minutes and similar total time around 486 minutes. Furthermore, we note that there was a decrease in the intraservice time by 23 minutes and the intraservice time ratio for this code suggests that the RUC -recommendation is too high. We proposed a work RVU of 23.53 for CPT code 35602based on a direct crosswalk to CPT code 32669 (*Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)*). We note that CPT code 35602was also valued by the RUC using a crosswalk code to maintain relativity within the family.

The RUC's recommended work RVUs do not reflect surveyed drops in work time (from 173 minutes to 150 minutes) for CPT code 35602and we are therefore selecting a crosswalk code that more accurately captures this decrease in the surveyed times. CPT code 32669 shares the same intraservice work time of 150 minutes as compared with CPT code 35602, it has a slightly higher total time (502 minutes as compared with 486 minutes), and both of these codes also contain two postoperative office visits in their global periods. We are supporting this proposed work RVU of 23.53 with a pair of other 090-day global codes with similar work time values, with a lower bracket of CPT code 22612 (*Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)*) at a work RVU of 23.53 and an upper bracket of CPT code 35666 (*Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery*) at an RVU of 23.66.

We proposed the RUC-recommended direct PE inputs for all the codes in this family.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally agreed with the CMS proposal of the RUC-recommended direct PE inputs for CPT codes 33880, 33881, 33883, 33886, 33882 and 35602 without refinement.

Response: We appreciate the commenters' support for the CMS proposal of the RUC-recommended direct PE inputs for CPT codes 33880, 33881, 33883, 33886, 33882 and 35602 without refinement.

Comment: Several commenters stated that there appeared to be an issue regarding the correct valuation of CPT codes 33880, 33881, 33883 and 33886 resulting from a mathematical error in the utilization crosswalk. The commenters stated that CMS double-counted the utilization for the new codes, most likely due to a misinterpretation attributable to the text in the RUC's utilization crosswalk recommendations stating, "Bundled into 33880" instead of "Savings" (bundled into 33880). The commenters stated that there was a discrepancy of 25,176 work RVUs included in the CMS utilization assumptions compared to what the RUC originally submitted and suggested CMS to correct the mathematical error on which the current work RVUs for CPT codes 33880, 33881, 33883 and 33886 are based.

Response: We appreciate the feedback from the commenters on the utilization crosswalk involving these codes. After reviewing the subject, we agree that there was an unintended technical error involving the utilization crosswalk for CPT codes 33880, 33881, 33883 and 33886 due to a misinterpretation of how the RUC made its recommendations. We are therefore finalizing a correction to this technical error in this final rule.

Comment: A few commenters disagreed with CMS' proposed direct crosswalks and work RVU recommendations for all six codes in this family. Commenters requested the need for CMS to adjust the work RVUs for the Thoracic Endovascular Aortic Repair (TEVAR) code family to reflect the complexity and intensity of these procedures. The commenters expressed that these procedures incorporate significant pre-service planning, intraoperative complexity, and extensive post-operative care that were not fully captured in the original code set or existing comparators. Additionally, the commenters stated that bundling radiographic supervision and interpretation with selective catheter codes into the primary TEVAR codes, along with the deletion of bypass codes, simplifies coding but increases procedure complexity. Commenters agreed with CMS that the two components of work are time and intensity, and decreases in the surveyed work time should typically be reflected in decreases to the work RVU, however, a commenter stated that with TEVAR, the intensity has increased substantially, which they believe should result in less reduction in the work RVU.

Response: We appreciate the commenters for their comments. We continue to believe that the RUC-recommended work RVUs do not appear to fully account for the overall decrease in the work times. We continue to believe that the proposed values for the work RVUs for all of the codes in this code family are accurate. The comparator codes selected account for intensity as well as time required for this service; we note, for example, that the intensity of each code in the family is increasing over its current value at our proposed work valuations.

Comment: Several commenters disagreed with CMS' proposed direct crosswalks and work RVU recommendations, stating that they do not accurately reflect the work and intensity required, especially given the risks such as paralysis and strokes associated with TEVAR. The commenters suggested that CMS finalize the RUC-recommended work RVUs that are based on robust survey data and detailed

clinical vignettes, reflecting modern practice and the elevated risks involved which were not present when the codes were initially valued.

Another commenter expressed concerns about the proposed work RVUs for the revised and new CPT codes within the TEVAR procedures. The commenter noted that TEVAR procedures have grown in complexity and risk profile since their initial FDA approval in 2005, and the recent approval of thoracic branch endoprosthesis (TBE) in 2022 has expanded the range of treatable aortic pathology. The commenter maintained that time alone does not fully capture the complexity and intensity of TEVAR procedures and urges CMS to finalize the RUC recommendations to ensure accurate valuation of these life-saving procedures. Another commenter noted with the improvement of device technology, a broader range of patients are treated with TEVAR.

Response: We appreciate the commenters for their comments. We understand the concerns raised by commenters stating that the new six-code family for TEVAR was developed to align with current clinical practices and CPT coding standards. We appreciate that the new procedures incorporate significant pre-service planning, intraoperative complexity, and extensive post-operative care that were not fully captured in the original codes. While we appreciate the recommendations presented by the commenters as it pertains to the work RVUs, several recommendations rely more on the relativity among the subspecialty. We continue to believe that looking at the relativity across the fee schedule allows for better relativity between codes.

Comment: A few commenters noted that TEVAR codes appropriately support automatic co-surgeon involvement due to the inherent complexity and intensity of these interventions and pointed out in contrast, all the crosswalk codes identified necessitate additional documentation to justify co-surgeon involvement. Commenters felt this supported increased intensity and thus a higher work RVU.

Response: With regard to the commenter's concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same specialty to serve as an appropriate crosswalk.

We continue to believe that our proposed valuations, based on the crosswalks selected, more accurately value these codes since they do not result in the sizable increases in intensity as recommended by the RUC. We maintained relativity between the codes in this family with similarly timed codes.

Comment: Several commenters disagreed with the proposed work RVU of 27.00 for CPT code 33880 and stated that CMS should finalize the RUC-recommended work RVU of 30.00. Commenters stated that the CMS direct crosswalk valuation based on CPT code 32672 relies too heavily on decreases of intraservice time and does not accurately account for the overall measured intensity required to perform this service. Commenters stated that CPT code 33880 requires more than 100 minutes of pre-service evaluation time which includes extensive imaging review and advanced 3D planning due to risks which are not present in any other surgery. Commenters stated that the intensity of the service was reflected in the RUC's recommended valuation and pointed to the two key reference codes from the RUC survey for support.

Response: We disagree with the commenters and continue to believe that our proposed work RVU of 27.00 for CPT code 33880 is a more accurate valuation. As we stated in the proposed rule, the RUC's recommended work RVU of 30.00 was higher than nearly all of the other 90-day global codes with similar time values and would not maintain relativity with other 90-day global period codes with an intraservice time of 120 minutes and similar total time around 546 minutes. The surveyed intraservice time for CPT code 33880 is decreasing from 225 minutes to 120 minutes (47 percent) while the work RVU is would only decrease from the current 34.58 to 30.00 (13 percent) if we were to finalize the RUC's recommended value. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We believe that it is more accurate to propose a work RVU of 27.00 to capture these decreases in surveyed intraservice time; we also note that our proposed valuation maintains the current intensity for CPT code 33880 instead of resulting in a significant increase as under the RUC's recommended value.

Comment: Several commenters disagreed with the proposed work RVU of 22.53 for CPT code 33881 and stated that CMS should finalize the RUC-recommended work RVU of 26.75. Commenters

stated that the CMS direct crosswalk valuation based on CPT code 43820 relies too heavily on decreases of intraservice time and does not accurately account for the overall measured intensity required to perform this service. Commenters stated that the proposed valuation did not reflect the intensity of a procedure with risks of permanent paralysis and anterior or posterior circulation strokes; commenters also pointed to the two key reference codes from the RUC survey for support.

Response: We disagree with the commenters and continue to believe that our proposed work RVU of 22.53 for CPT code 33881 is a more accurate valuation. As we stated in the proposed rule, the surveyed intraservice time for CPT code 33881 is decreasing from 200 minutes to 110 minutes (45 percent) while the work RVU is would only decrease from the current 29.58 to 26.75 (10 percent) if we were to finalize the RUC's recommended value. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We believe that it is more accurate to propose a work RVU of 22.53 to capture these decreases in surveyed intraservice time for CPT code 33881.

Comment: Several commenters disagreed with the proposed work RVU of 35.00 for CPT code 33882 and stated that CMS should finalize the RUC-recommended work RVU of 39.00. Commenters stated that the CMS direct crosswalk valuation based on CPT code 33390 relies too heavily on decreases of intraservice time and does not accurately account for the overall measured intensity required to perform this service. Commenters stated that the proposed valuation did not reflect the intensity/complexity of the procedure that requires fenestration alignment and selective catheterization of the subclavian artery, which reflects both the technical sophistication and elevated risk of spinal cord ischemia requiring surgeon-led monitoring. Commenters also pointed to the two key reference codes from the RUC survey for support.

Response: We disagree with the commenters and continue to believe that our proposed work RVU of 35.00 for CPT code 33882 is a more accurate valuation. As we stated in the proposed rule, we found that the RUC-recommended work RVU of 39.00 does not maintain relativity with other 90-day global period codes with the same intraservice time of 180 minutes and similar total time around 621 minutes. We also note that if we were to finalize the RUC's recommended work RVU, CPT code 33882

would be assigned an intensity significantly higher than the rest of this code family. While we agree with the commenters that all of these procedures carry significant patient risks, which is reflected in high intensity values for all of them, we do not agree that CPT code 33882 should have an anomalously high intensity relative to the other Thoracic Branch Endograft Services procedures. By proposing a work RVU of 35.00, our proposed intensity for CPT code 33882 maintains relativity with the rest of its code family.

Comment: Several commenters disagreed with the proposed work RVU of 19.91 for CPT code 33883 and stated that CMS should finalize the RUC-recommended work RVU of 24.25. Commenters stated that the CMS direct crosswalk valuation based on CPT code 44320 relies too heavily on decreases of intraservice time and does not accurately account for the overall measured intensity required to perform this service. Commenters stated that although the intraservice time was the same between CMS' crosswalk code and the surveyed code, CPT code 44320 has very low intensity/complexity comparatively whereas CPT code 33883 is an extension endograft, so the risk of spinal cord ischemia and coverage of the subclavian is similar or even more than CPT code 33881. Commenters also pointed to the two key reference codes from the RUC survey for support.

Response: We disagree with the commenters and continue to believe that our proposed work RVU of 19.91 for CPT code 33883 is a more accurate valuation. As we stated in the proposed rule, we found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 90 minutes and similar total time around 486 minutes. The surveyed intraservice time for CPT code 33883 is decreasing from 120 minutes to 90 minutes (-25 percent) while the work RVU would increase from the current 21.09 to 24.25 (+15 percent) if we were to finalize the RUC's recommended value. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs, not increases. We believe that it is more accurate to propose a work RVU of 19.91 to capture these decreases in surveyed intraservice time for CPT code 33883.

Comment: Several commenters disagreed with the proposed work RVU of 19.91 for CPT code 33886 and stated that CMS should finalize the RUC-recommended work RVU of 23.50. Commenters stated that the CMS direct crosswalk valuation based on CPT code 44320 relies too heavily on decreases

of intraservice time and does not accurately account for the overall measured intensity required to perform this service. Commenters stated that although the intraservice time was the same between CMS' crosswalk code and the surveyed code, CPT code 44320 has very low intensity/complexity comparatively whereas CPT code 33886 is an extension endograft, so the risk of spinal cord ischemia and coverage of the artery of Adamkiewicz was highest for the service. Commenters stated that using a colostomy code as a comparator is inappropriate and noted that endovascular major aortic surgery should not be compared with straightforward intra-abdominal procedures; commenters also pointed to the two key reference codes from the RUC survey for support.

Response: We disagree with the commenters and continue to believe that our proposed work RVU of 19.91 for CPT code 33886 is a more accurate valuation. As we stated in the proposed rule, we found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 90 minutes and similar total time around 486 minutes. The surveyed intraservice time for CPT code 33886 is decreasing from 100 minutes to 90 minutes (-10 percent) while the work RVU would increase from the current 18.09 to 23.50 (+30 percent) if we were to finalize the RUC's recommended value. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs, not increases. We believe that it is more accurate to propose a work RVU of 19.91 to capture these decreases in surveyed intraservice time for CPT code 33886.

We also disagree with the commenters that the use of CPT code 44320 as a valuation crosswalk was inappropriate. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters disagreed with the proposed work RVU of 23.53 for CPT code 35602 and stated that CMS should finalize the RUC-recommended work RVU of 27.40. Commenters stated that the direct crosswalk valuation based on CPT code 32669 does not accurately account for the

overall measured intensity required to perform this service; commenters also pointed to the two key reference codes from the RUC survey for support.

Response: As we stated in the proposed rule, we found that the RUC-recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 150 minutes and similar total time around 486 minutes. Our proposed work RVU of 23.53 for CPT code 35602 maintains similar intensity to the predecessor CPT code (33891) as well as the rest of this code family which suggests that it is a more accurate valuation.

After consideration of the public comments, we continue to believe that the proposed valuation accurately reflects the typical work involved in furnishing Thoracic Branch Endograft services. Therefore, for CY 2026, we are finalizing our proposed work RVUs and direct PE inputs for CPT codes 33880, 33881, 33883, 33886, 33882 and 35602.

(9) Lower Extremity Revascularization (CPT codes 37254, 37255, 37256, 37257, 37258, 37259, 37260, 37261, 37262, 37263, 37264, 37265, 37266, 37267, 37268, 37269, 37270, 37271, 37272, 37273, 37274, 37275, 37276, 37277, 37278, 37279, 37280, 37281, 37282, 37283, 37284, 37285, 37286, 37287, 37288, 37289, 37290, 37291, 37292, 37293, 37294, 37295, 37296, 37297, 37298, and 37299)

In October 2018, three CPT codes (37225, 37227, and 37229) were flagged by the Relativity Assessment Workgroup for high-cost supplies review, leading to a series of significant changes in the lower extremity revascularization (LER) code family. After multiple reviews and discussions between 2018 and 2024, the CPT Editorial Panel ultimately created four new subsections and 46 new codes to replace the existing 16 codes (CPT codes 37220-37235) for LER services. According to the RUC, this comprehensive update was driven by technological advances, changes in practice settings, and the need to better differentiate between a stenosis (that is, a straightforward lesion) and an occlusion (that is, a complex lesion) procedures. These codes were surveyed for the September 2024 RUC meeting and recommendations submitted to CMS for consideration in the CY 2026 PFS final rule. See Table A-E5 for a summary of the codes, and their long descriptors.

According to the RUC, not all codes received a full survey from participants. Eleven selected core codes had complete survey responses from all respondents, while the remaining 35 codes underwent an abbreviated survey process. The 35 abbreviated survey codes were split into two groups and survey

respondents only received one of those two groups along with the 11 core codes. There were two notable changes made to the abbreviated survey. First, survey respondents were provided with one of the anchor codes as a comparator instead of using a reference service list; second, survey respondents were only asked one question per abbreviated code in the intensity/complexity section. Therefore, respondents did not complete all elements of the abbreviated survey, as some elements were pre-populated. We note that this method could potentially introduce inaccuracies and bias in the survey outcomes.

For CY 2026, we proposed the RUC-recommended work RVUs for all 46 CPT codes. However, we have concerns about the survey data, specifically regarding the small sample size and large variations in responses. We encouraged commenters to submit additional data for our consideration in determining the valuation of work and direct PE inputs for these CPT codes. Table A-E5 also shows the proposed work RVUs for the 46 CPT codes:

TABLE A-E5: CPT LONG DESCRIPTORS AND PROPOSED WORK RVUS FOR LOWER EXTREMITY REVASCULARIZATION PROCEDURES

CPT Code	Long Descriptors	Proposed Work RVUs
37254	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	7.30
+37255	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.00
37256	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	10.75
+37257	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.89
37258	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	8.75
+37259	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the*	4.00

CPT Code	Long Descriptors	Proposed Work RVUs
	artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	
37260	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	12.69
+37261	*Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel*	4.25
+37262	*Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)*	3.00
37263	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	7.75
+37264	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.00
37265	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	10.50
+37266	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.00
37267	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	8.75
+37268	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging*	3.73

CPT Code	Long Descriptors	Proposed Work RVUs
	guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	
37269	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	14.75
+37270	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	5.00
37271	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	9.00
+37272	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel*	4.00
37273	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	12.63
+37274	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	5.50
37275	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	11.00
+37276	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when*	4.25

CPT Code	Long Descriptors	Proposed Work RVUs
	performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	
37277	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	15.00
+37278	*Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	6.00
+37279	*Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)*	4.00
37280	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	9.80
+37281	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.00
37282	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	12.31
+37283	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.26
37284	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	10.00
+37285	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	3.34

CPT Code	Long Descriptors	Proposed Work RVUs
37286	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	13.46
+37287	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	5.00
37288	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	13.50
+37289	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.75
37290	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel*	17.00
+37291	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)*	6.50
37292	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel*	15.00
+37293	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	6.50
37294	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including*	18.00

CPT Code	Long Descriptors	Proposed Work RVUs
	transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	
+37295	*Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure*	8.16
37296	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel*	11.00
+37297	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)*	4.00
37298	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel*	13.70
+37299	*Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure*	5.00

We proposed the RUC-recommended PE inputs for all 46 CPT codes, with several revisions to address discrepancies found in the documentation. Regarding the drug-coated balloon (SD382), which is priced at $2,343.33, the RUC recommendations show inconsistent quantity allocations across different code sets. The RUC documentation specifies two units for the initial vessel and one unit for additional vessels in CPT codes 37263 - 37266 and 37271 - 37274. However, for CPT codes 37267 - 37268 and 37275 - 37276, only one unit is listed for the initial vessel. Furthermore, CPT codes 37269 - 37270 and 37277 - 37279 have no quantity values specified at all. To address these inconsistencies, we propose updating the initial vessel quantities to one unit of the SD382 drug-coated balloon for CPT codes 37263, 37265, 37271, and 37273, while maintaining one unit for additional vessels.

The RUC recommends a quantity of two for supply code SD379 (drug eluting stent, tibial) for four CPT codes in the tibial and peroneal vascular territory, CPT codes 37286, 37287, 37294, and 37295. The RUC-recommended quantity exceeds the number of units of supply code SD266 (stent, self-expanding 2-5 mm XPERT (Abbott)) currently used in CPT code 37230, 37234, 37231, and 37235, respectively. We proposed to reduce the quantity from two to one for supply code SD379 (drug eluting stent, tibial) in each of the four CPT codes 37286, 37287, 37294, and 37295.

For this code family, the RUC recommended 34 minutes of equipment time for the Professional PACS Workstation (ED053). We believe this recommendation contains an unintended technical error regarding the equipment time. Therefore, we proposed using the standard equipment formula for the professional PACS workstation, which calculates equipment minutes as the sum of intraservice work time plus half of the preservice work time.

While we proposed the listed refinements above, we sought comments on whether we should create G-codes to describe the use of high-cost supplies. Alternatively, we sought comments on whether we could use the Hospital Outpatient Prospective Payment System (OPPS) mean unit cost data (MUC) to accurately price these services and their supplies based on how these supplies are paid for in the hospital setting. We sought comments on whether there is additional information we should consider in establishing proposed payments for these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments on our proposal to update the initial vessel quantities to one unit of the SD382 drug-coated balloon for CPT codes 37263, 37265, 37271, and 37273. Some commenters stated that CPT codes 37263, 37265, 37271 and 37273 would typically require two drug-coated balloons, whereas their corresponding add-on codes (37264, 37266, 37272 and 37274) would typically only require one drug-coated balloon for each additional vessel. For CPT codes 37263, 37265, 37271, and 37273, the commenters stated that the RUC recommendation of two drug-coated balloons was necessary because drug-coated balloons can only deliver their therapeutic payload to one area during a single inflation according to FDA instructions, and these procedures involve treating long segments of arterial disease in the superficial femoral/popliteal region that typically require coverage by two separate

balloons. However, regarding CPT codes 37267, 37268, 37275, and 37276, commenters stated that only one unit is appropriate for the initial vessel. Commenters noted that these codes are most often reported for procedures involving the common femoral artery or the profunda femoris artery segment of the femoropopliteal region, which are shorter vessels with shorter disease segments that can be effectively treated with a single drug-coated balloon. Regarding CPT codes 37269, 37270, 37277, and 37278, commenters stated that covered stents are typically used in these procedures, making drug-coated balloons unnecessary since the treated segments are covered by fabric-coated stents. For CPT code 37279, commenters stated that the practice expense inputs are limited to the additional work associated with Intravascular Lithotripsy, which is performed in addition to the base codes of the family. Therefore, additional drug-coated balloons were not included in this portion of the code family as they are already accounted for in the appropriate base codes.

Response: We appreciate the commenters for the additional information provided. After consideration of the public comments, we agree that the direct PE inputs for CPT codes 37263, 37265, 37271, and 37273 should include two drug-coated balloons (SD382) per code, as we are persuaded by commenters that two balloons are typically required due to the length of disease in the superficial femoral and popliteal segments.

Comment: We received comments supporting the RUC's recommended quantity of two units for drug eluting stent, tibial (SD379) in the tibial segment complex CPT codes 37286, 37287, 37294, and 37295. Commenters stated that these procedures typically require two drug-eluding stents each, whereas tibial segment straightforward taking place in CPT codes 37284 and 37285 only require one drug-eluding stent each. Commenters stated that the length of the vessel is the same between a straightforward and a complex lesion for CPT codes 37284-37287, but that for tibial interventions, surgeons are typically working with stents that are 38mm long. Commenters stated that complex lesions are typically quite long and as such it is most typical to use 2 stents in the tibial segment for the complex lesions described by CPT codes 37286-37287 and 37294-37295. Some commenters stated that closer to 4 stents would be appropriate for these two codes whereas other commenters stated that in some cases 4 or 5 stents would be required in the tibial segment.

Other commenters stated that since the time that the previous code set was valued, the stents included in that coding's PE supply costs (the self expanding 2-5 mm stent described by supply code SD266) have been removed from the market and are no longer used, which is why the RUC recommended the use of the SD379 tibial stent. Commenters stated that the complex CPT codes (37286, 37287, 37294 and 37295) represent the minority of tibial interventions and that it will be much more likely for tibial interventions to not require stent placement. Commenters concluded that many more of the treatments will be simple stenoses (straightforward lesions) and if stent placement is performed it will only require a single drug eluting stent in most cases.

Response: We appreciate the commenters for the additional information provided. After consideration of the public comments, we were convinced that the use of a second tibial stent would be typical for CPT codes 37286-37287 and 37294-37295. We are therefore finalizing the RUC-recommended two units for the drug eluting stent, tibial (SD379) supply for CPT codes 37286, 37287, 37294 and 37295.

Comment: The commenters recommended CMS to adopt a clinically grounded, evidence-based definition of "complex lesions" within the new LER code set, aligned with clinical literature and professional society guidelines, to ensure accurate coding and payment. According to a commenter, the clinical literature and established professional society guidelines characterize complex lesions in LER as involving one or more of the following features: lesion length greater than 15 cm, moderate to severe arterial calcification, chronic total occlusions (CTOs), in-stent restenosis, prior failed endovascular intervention, involvement of the popliteal artery (particularly P2/P3 segments), multilevel or multivessel disease, and single-vessel runoff.

Response: We appreciate the commenters for the additional information provided. We encourage them to work with the CPT Editorial Panel to develop a clinically grounded, evidence-based definition of "complex lesions" within the new LER code set, consistent with clinical literature and professional society guidelines.

Comment: Many commenters encouraged CMS to establish G-codes for high-cost supplies as it could improve billing accuracy and ensure appropriate reimbursement for expensive medical devices and supplies used in patient care. Commenters also stated that, if CMS intends to utilize Outpatient

Prospective Payment System (OPPS) cost data to establish pricing for services and supplies within the PFS the agency should provide a comprehensive and detailed methodological proposal through future rulemaking.

Response: We appreciate the commenters for their feedback regarding the LER code set.. We believe that the OPPS cost data might be a useful source of information and will consider it for future rulemaking. We are open to feedback from interested parties.

Comment: Several commenters thanked CMS for creating a new supply pack for the angiography services (SA142) associated with this code family. However, commenters stated that the SA142 supply pack was not assigned to the applicable codes in the LER family (CPT codes 37254, 37256, 37258, 37260, 37263, 37265, 37267, 37269, 37271, 37273, 37275, 37277, 37280, 37282, 37284, 37286, 37288, 37290, 37292, 37294, 37296, and 37298). Commenters provided a list of 20 supply components that together constituted the SA142 supply pack and requested that CMS remove these supply inputs from the LER code family, to be replaced by the SA142 supply pack.

Response: The direct PE inputs recommended by the RUC for this code family listed all of the individual components for the SA142 supply pack separately, rather than bundling them into a supply pack, and at the time it was not clear what supply components constituted the SA142 pack. However, in light of the additional information provided by the commenters, we will remove the supply items that make up the SA142 supply pack from the associated LER codes and replace them with the SA142 pack as requested.

In reviewing the information provided by commenters, we also noticed that the supply components of the SA142 pack as listed by commenters differed from the supply inputs contained within the LER codes in a few places. Specifically, the codes only contained one sterile basin (SJ079) instead of two, they only contained one plastic towel clamp (SD208) instead of four, and they did not contain a lidocaine control syringe (listed under SC051) at all. Since these supplies were not recommended as typical for the LER codes, we have removed them from the SA142 supply pack and updated its pricing to $62.26. With these changes, the price of the SA142 supply pack now matches the sum of its components, as well as matching the price of the supply components removed from the LER codes. Therefore, there is

no change in the direct costs of the associated codes due to the replacement of the individual supplies with the SA142 pack. The contents of the SA142 supply pack are listed in this section for reference:

TABLE A-E6: Contents of SA142 Angiography Supply Pack

SA142 Angio Pack Contents	Supply Code	Corresponding Supply list Components	Price Per Unit	Units	Total: $62.26
10 cc syringe	SC051	syringe 10-12ml	0.21	4	$ 0.84
Bowl, sterile	SJ079	basin, sterile 500cc	3.51	1	$ 3.51
gauze	SG055	gauze, sterile 4in x 4in	0.19	20	$ 3.80
marker, regular tip	SK075	skin marking pen, sterile (Skin Skribe)	1.62	1	$ 1.62
dome cover	SB008	drape, sterile, c-arm, fluoro	5.38	1	$ 5.38
blue towels	SB019	drape-towel, sterile 18in x 26in	0.47	4	$ 1.88
scalpel	SF007	blade, surgical (Bard-Parker)	0.68	1	$ 0.68
back table cover	SB014	drape, sterile, three-quarter sheet	3.46	1	$ 3.46
20cc syringe	SC053	syringe 20ml	0.83	4	$ 3.32
drape, femoral	SB009	drape, sterile, femoral	9.15	1	$ 9.15
medicine cup	SL157	cup, sterile, 8 oz	0.58	1	$ 0.58
label sheet	SL198	label, vial	0.02	9	$ 0.18
scissor	SA027	kit, scissors and clamp	0.82	1	$ 0.82
surgical gowns x 2	SB028	gown, surgical, sterile	5.13	2	$ 10.26
18 G needle	SC027	needle, 18-19g, filter	0.21	1	$ 0.21
25 G needle	SC028	needle, 18-26g 1.5-3.5in, spinal	9.96	1	$ 9.96
needle counter	SD120	styrofoam block, high density (3in- 12in-12in)	1.86	1	$ 1.86
towel clamps (plastic disposable)	SD208	towel clamp, plastic	0.76	1	$ 0.76
Guidewire bowl	SD171	guidewire bowl w-lid, sterile	3.99	1	$ 3.99

After consideration of public comments, we are finalizing the proposed work RVUs and direct PE inputs for the codes in the LER family, with the previously mentioned increase to two drug-coated balloon (SD382) supplies for CPT codes 37263, 37265, 37271, and 37273 as well as two drug eluting tibial stent (SD379) supplies for CPT codes 37286, 37287, 37294 and 37295. Lastly, we are also finalizing the inclusion of a new supply pack for angiography services (SA142) as previously described.

(10) Irreversible Electroporation of Tumors (CPT codes 47384 and 55877)

At the September 2024 CPT Editorial Panel Meeting, two new CPT codes were created for reporting percutaneous irreversible electroporation ablation of one or more tumors: CPT codes 47384 (*Ablation, irreversible electroporation, liver, 1 or more tumors, including imaging guidance, percutaneous*) and 55877 (*Ablation, irreversible electroporation, prostate, 1 or more tumors, including*

imaging guidance, percutaneous). These new CPT codes were surveyed at the January 2025 AMA RUC meeting. For CY 2026, we are proposing the RUC-recommended work RVUs of 9.41 for CPT code 47384 and 13.50 for CPT code 55877.

We proposed the following refinements to the direct PE inputs for CPT code 47384. We disagreed with the RUC recommendation to use the standard 90-day global pre-service clinical labor times in the facility setting for CPT code 47384 since this is a 0-day global procedure. We did not agree that it would serve the interests of relativity to use the 90-day global clinical labor standard times for a 0-day global service. Therefore, we proposed the standard 000/010 global day extensive pre-service clinical labor times in the facility setting, resulting in the following changes: the minutes associated with CA002 (*Coordinate pre-surgery services (including test results)*) are reduced from 20 minutes to 10 minutes; the minutes associated with CA003 (*Schedule space and equipment in facility*) are reduced from 8 minutes to 5 minutes; the minutes associated with CA004 (*Provide pre-service education/obtain consent*) are reduced from 20 minutes to 7 minutes; and the minutes associated with CA005 (*Complete pre-procedure phone calls and prescription*) are reduced from 7 minutes to 3 minutes.

We proposed the RUC-recommended direct PE inputs for CPT code 55877 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed work RVU and direct PE inputs for this code family.

Response: We appreciate the commenters for their support.

Comment: Some commenters stated that the level of clinical staff work required for irreversible electroporation is extensive and recommended CMS accept the times in the RUC recommended pre-service package. The reference code selected to assist in establishing direct PE inputs was CPT code 33361 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach*), which is also a 0-day global code. Commenters stated that it serves as an example for the pre-service clinical staff time package, which encompasses the comprehensive use of clinical staff in a facility setting. Commenters also stated that they believe the level of clinical staff work required for

irreversible electroporation is extensive and therefore suggested CMS to accept the standard 90-day global pre-service clinical labor times in the facility setting for CPT code 47384.

Response: After reviewing the comments, we remain unconvinced that the information provided would support the need for the standard 90-day global pre-service clinical labor times in the facility setting for CPT code 47384 since this is a 0-day global procedure. We continue to believe that the standard 000/010 global day pre-service clinical labor times in the facility setting is appropriate, and that the recommended standard 90-day global pre-service clinical labor times in the facility setting for CPT code 47384 would not be typical for the procedure. Therefore, we are finalizing the standard 000/010 global day pre-service clinical labor times for CPT code 47384, as proposed.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Irreversible Electroporation of Tumors family as proposed.

(11) Endoscopic Sleeve Gastroplasty (CPT code 43889)

In September 2024, CPT approved the addition of a new code to report transoral gastric restrictive procedures using an endosurgical approach. CPT code 43889 (*Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed)* was surveyed for the January 2025 RUC meeting.

The RUC-recommended a direct crosswalk to CPT 36832 (*Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure))* with a work RVU of 13.50. During the RUC prefacilitation meeting, 1 unit of CPT code 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and a moderate level of medical decision making)* was removed from the postoperative period, and 20 minutes of work time was added into the immediate post-service time. The RUC also revised the global period of CPT code 43889 to reduce the work and time value of CPT code 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter)* to half of the original value. We believe the RUC partially applied the 23-hr policy when it applied the policy to the immediate postservice time but not to the work RVU. The 23-hour policy established in the CY 2011 PFS final rule (75 FR 73226) applies to services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours. We

discussed in the CY 2011 PFS final rule that we believe the value of these codes should not reflect work that is typically associated with an inpatient service. We believe the 23-hour policy in its entirety should be applied to CPT code 43889, which includes the work RVUs along with the immediate post service time. Following the valuation methodology we established for the 23-hour policy in the CY 2011 PFS final rule (75 FR 73226), we proposed a work RVU of 12.56 for CPT code 43889. The steps are as follows:

Step (1): The RUC appropriately reduced the hospital discharge day management service included in the global period from 1 to 0.5; therefore, we will skip this step.

Step (2): 13.50 – 1.39** = 12.11

Step (3): 12.11 + (20 minutes x 0.0224)*** = 12.56 RVUs

* Value associated with ½ hospital day discharge management service.

** Value associated with an inpatient hospital visit, CPT code 99232.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

We proposed the RUC-recommended direct PE inputs for CPT code 43889without refinement.

We proposed a work RVU of 12.56 for CPT code 43889 based on application of the 23-hour policy. We received several comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the RUC recommended work RVU and stated that the crosswalk value is most appropriate. Commenters noted that the RUC recommendation was based on a crosswalk to CPT code 36832, which does not contain any inpatient hospital visits. Therefore, the need for a visit to be removed is negated, as the underlying crosswalked reference code also does not include inpatient hospital visits. Other commenters recommended that CMS consider using the RUC survey data instead of the crosswalk recommendation in determining the appropriate valuation. A few commenters stated that should CMS decide not to use the survey and base the value on the RUC-recommended crosswalk, CMS should not apply the 23-hour policy since the crosswalk CPT code 36832 already had the 23-hour policy applied. Overall, these commenters were concerned that adjusting the work RVU for CPT code 36832 would increase costs and lead to access issues for beneficiaries.

Response: We appreciate the information provided by commenters. We understand that the inpatient hospital visit was removed from the code valuation and therefore not reflected in the resulting work RVU. We continue to believe the value of these codes should not reflect work that is typically associated with an inpatient service and that the 23-hour policy should be applied in its entirety including the work RVUs along with the immediate post service time.

After reviewing the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 43889 as proposed.

(12) Transurethral Robotic-assisted Resection of Prostate (CPT codes 52500, 52601, 52630, 52648, 52649, and 52597)

In May 2024, the CPT Editorial Panel created a new CPT code to report transurethral robotic-assisted waterjet resection of the prostate, including ultrasound guidance: CPT code 52597 (*Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed*). CPT code 52597 was surveyed for the September 2024 RUC meeting along with the existing codes in this code family: CPT code 52500 (*Transurethral resection of bladder neck (separate procedure)*), CPT code 52601 (*Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*), CPT code 52630 (*Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*), CPT code 52648 (*Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/ or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)*), and CPT code 52649 (*Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)*). For CY 2026, the RUC recommended a work RVU of 6.00 for CPT code 52500, a work RVU of 10.25 for CPT code 52597, a

work RVU of 10.00 for CPT code 52601, a work RVU of 6.55 for CPT code 52630, a work RVU of 10.05 for CPT code 52648, and a work RVU of 14.56 for CPT code 52649.

We proposed the RUC-recommended work RVU of 6.00 for CPT code 52500, the work RVU of 10.25 for CPT code 52597, the work RVU of 10.00 for CPT code 52601, the work RVU of 6.55 for CPT code 52630, and the work RVU of 10.05 for CPT code 52648.

We note that the RUC will be placing CPT code 52597 on the New Technology/New Services list and CPT code 52597 will be re-reviewed by the RUC in 3 years to ensure correct valuation, patient population, and utilization assumptions. Also, we received external input suggesting the RVU for CPT code 52597 should be higher than the RUC recommendation of 10.25 and that an RVU of 14.56 (same as the RUC recommendation for CPT code 52649) would be more appropriate. However, given the survey times and comparisons to similarly timed codes with similar intensity, an RVU of 14.56 for CPT code 52597 would not be accurate. The RUC's valuation for CPT code 52597 is typical for a procedure code with the same work time values (that is, 60 minutes intraservice time and 234 minutes of total time). With all of these considerations, we believe that proposing a work RVU of 10.25 for CPT code 52597 maintains relativity with the other CPT codes in this family.

For CPT code 52649, we disagree with the RUC-recommended work RVU of 14.56 and we are proposing an RVU of 13.00 instead, based on a crosswalk to CPT code 53500 (*Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (for example, postsurgical obstruction, scarring)*). We believe the RUC-recommended work RVU of 14.56 is too high and should be lowered due to the decrease in intraservice time of 30 minutes (from 120 minutes to 90 minutes), and the decrease in total time by 16 minutes (from 279 minutes to 263 minutes). An RVU of 13.00 for CPT code 52649 is supported by the range of CPT code 64912 (*Nerve repair; with nerve allograft, each nerve, first strand (cable)*) with an RVU of 12.00, the same intraservice time and 272 minutes of total time, and by CPT code 15730 (*Midface flap (that is, zygomaticofacial flap) with preservation of vascular pedicle(s)*) with an RVU of 13.50, the same intraservice time and 255.5 minutes of total time.

We proposed the RUC-recommended direct PE inputs for CPT codes 52500, 52597, 52601, 52630, and 52649 without refinement. For CPT code 52648, we proposed to remove the 6 minutes of clinical labor time for CA021 (Perform procedures/services—NOT directly related to physician work

time). Therefore, the equipment time reported under EF031 (table, power) has also been reduced by 6 minutes (from 95 minutes to 89 minutes) to reflect the removal of clinical labor activity CA021 from CPT code 52648. We note that CPT code 52648 is performed in the facility setting only and the standard is 0 minutes for CA021 in the facility. Also, supply item SL036 (cup, biopsy-specimen sterile 4oz) was reported as a non-facility PE input for CPT code 52648. Since CPT code 52648 is only performed in the facility setting, we believe inclusion of supply item SD036 as a non-facility PE input was unintentional and therefore proposed to remove it.

Comment: Many commenters disagreed with the proposed work RVU of 10.25 for CPT code 52601. Commenters stated that CPT code 52601 has been the standard of surgical management for benign prostatic hyperplasia (BPH) and that the typical operative time for the procedure has not changed and it demands continuous mental focus, physical effort, and advanced technical skill. Commenters stated that the proposed work RVU constituted a reduction of nearly 25 percent in payment and represented a serious miscalculation in the intensity and complexity of performing the service. Commenters stated that a reduction in payment risked disincentivizing urologists from providing these services, could pressure physicians to alter treatment recommendations, and undermined quality care for patients. Commenters recommended CMS to maintain the current work RVU of 13.16 for CPT code 52601 and to increase the work RVU of all other codes in the family by 31.6 percent (13.16 divided by 10.00) to provide fair and equitable compensation for the broad range of BPH treatments that urologists deliver.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 10.00, based on the RUC recommendation, remains the most accurate valuation for CPT code 52601. The surveyed intraservice work time for CPT code 52601 is decreasing from 75 minutes to 60 minutes, and although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. Given this reduction in surveyed work time, we do not believe that it would be appropriate to maintain the current work RVU of 13.16 for CPT code 52601; it is therefore not the case that the typical operative type for the procedure is unchanged as many commenters suggested. Similarly, we do not agree that it would be accurate or maintain relativity to increase the work RVU of all other

codes in this family by 31 percent which would result in anomalously high intensity values. We also note that the proposed work RVU of 10.00 brings the intensity of CPT code 52601 into alignment with the rest of this code family, as well as into alignment with many other 90-day global services elsewhere on the PFS.

Comment: Several commenters disagreed with the proposed work RVU of 13.00 for CPT code 52649 based on a crosswalk to CPT code 53500. Commenters stated that the 30-minute decrease in intraservice time from when this code was last surveyed in 2010 is the result of the diffusion of skilled surgeons performing this procedure nationally, and the increase in the size of the typical prostate being treated with laser enucleation has led to a significant increase in procedural intensity. A commenter stated that the reduction in time likely reflects advancements in technology and surgeon efficiency starting at month 1 of follow-up and remained improved for the entire follow-up period, rather than diminished work intensity. Commenters stated that CPT code 52649 should not be crosswalked to CPT code 53500, as CPT code 52649 is much more intense and complex to perform since it requires careful preservation of the prostatic capsule and bladder neck to prevent the formation of recto-urethral fistulae and bladder neck injury resulting in significant patient morbidity. Commenters stated that visualization is typically far superior when performing CPT code 53500 compared to CPT code 52649, and that there is no component of tissue morcellation with a rotational sharp-bladed device at all in CPT code 53500. Commenters requested that CMS finalize the RUC's recommended work RVU of 14.56 for CPT code 52649.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 13.00 is the most accurate valuation for CPT code 52649. The surveyed intraservice work time for CPT code 52649 is decreasing from 120 minutes to 90 minutes, and although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. Given this reduction in surveyed work time, we do not believe that it would be appropriate to maintain the current work RVU of 14.56 for CPT code 52649, which would result in a significant increase in intensity and place the code out of alignment with the rest of its family.

We also disagree with the commenters that CPT code 53500 is an inappropriate choice for a crosswalk code at the proposed work RVU of 13.00. CPT code 53500 is a transvaginal urethrolysis procedure including cystourethroscopy, with the same intraservice time of 90 minutes and a slightly longer total time (289 minutes as compared with 263 minutes) than CPT code 52649. CPT code 53500 typically requires sutures to close its transvaginal incision and carries risk of complications such as bleeding and urethral or bladder injury; we disagree that this procedure constitutes significantly less intensity as the commenters suggested. Furthermore, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. As such, we continue to believe that CPT code 53500 is an appropriate choice to use as a valuation crosswalk for CPT code 52649.

Comment: A commenter stated that CPT code 52649 should have a work RVU more aligned with the work RVU of CPT code 55867 at 19.53. The commenter stated that this valuation would appropriately reflect its technical complexity, equivalent anatomical outcomes to CPT code 55867, and alignment with cross-specialty benchmarks like knee arthroplasty (CPT code 27447), while accounting for the procedure's high skill demands, precision in endoscopic enucleation, and proven long-term efficacy in symptom relief and durability. The commenter also requested that CMS not increase the work valuation for CPT codes 52441 and 52442 which would penalize value and durability and encourage use of an index service that offloads costs into future episodes.

Response: As we stated previously in this section, we continue to believe that the proposed work RVU of 13.00 is the most accurate valuation for CPT code 52649. CPT code 55867 was also reviewed in this same CY 2026 PFS final rule, with a surveyed intraservice time of 180 minutes and a total time of 372 minutes. These work times are substantially longer than the intraservice time (90 minutes) and total time (263 minutes) of CPT code 52649; since the two components of work are time and intensity, and CPT code 55867 has double the intraservice work time, this accounts for the difference in the proposed work RVUs (13.00 and 19.53) of these two codes. Assigning a work RVU of 19.53 to CPT code 52649

would not be typical for this service and would create a rank order anomaly in terms of intensity. As for CPT codes 52441 and 52442, we did not make any proposals associated with them in this rule.

Comment: A commenter disagreed with the proposed work RVU of 10.25 for CPT code 52597 and requested a work RVU of 13.00 or 14.00 instead. The commenter stated that they were providing a new, robust empiric source of information based on an independent survey that yielded 163 responses with broad geographic representation from 33 jurisdictions. The commenter stated that the work RVUs aligned very closely between the 2024 targeted AMA RUC survey respondents and the independent 2025 real world attestation survey across the full spectrum of percentiles, with 25th percentile work RVUs of 13.00 and 14.00 respectively. The commenter also stated that additional empiric information from the clinical literature highlights the similarities in the duration and intensity of physician work between CPT code 52597 and laser enucleation of the prostate, which is typically performed with a Holmium laser (HoLEP), and coded as CPT code 52649. The commenter stated that these clinical similarities suggested that CPT code 52597 should be valued similarly to CPT code 52649 at a work RVU around 13.00 and not similarly to CPT code 53854 (*Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy*) at a work RVU of 5.93.

Response: We appreciate the submission of this additional survey data by the commenter. However, we disagree with the commenters and continue to believe that the proposed work RVU of 10.25, based on the RUC recommendation, remains the most accurate valuation for CPT code 52597. The RUC has a long history of using a mixture of targeted and random survey respondents for their survey process, as the targeted survey respondents who have personal experience with the procedure in question tend to overestimate its intensity. Our intention in seeking additional information is not to privilege once source over the other. Prioritizing the results of a targeted survey over the data from the data generated by random respondents would not be methodologically appropriate and could lead to inaccurate valuations.

We also have serious concerns about the specific independent survey data submitted by the commenter regarding CPT code 52597. It appears that this survey did not investigate the work times associated with CPT code 52597 and instead questioned the respondents what work RVU their hospital had paid them for performing the procedure. This is a reversal of our methodology for work valuation, in which the work RVU is derived based on both surveyed time data and the intensity of furnishing the

service itself. Although we appreciate that the commenter attempted to achieve a broad geographic representation, we also have concerns that this survey methodology overlooks potential geographic variations in payment as well as potential payment markups applied by hospitals.

We continue to believe that the proposed work RVU of 10.25 remains the most accurate valuation for CPT code 52597. Assigning a work RVU of 13.00 or 14.00 for CPT code 52597 as requested by the commenter would create a rank order anomaly within the rest of the code family, as CPT code 52597 would have roughly double the intensity of its peer codes. We do not believe that this would be typical for the procedure and therefore continue to believe that the proposed valuation of 10.25 is most accurate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they were concerned that updating the price of the cystoscopy visit supply pack (SA058) from $113.70 to $37.63 would cause drastic decreases in payment for physicians performing cystoscopy services in the office setting. The commenter stated that even though CMS finalized a 4-year phased transition of the SA058 pricing to soften the impact, the cut remains severe and that CMS should ensure the updated supply pack and equipment times accurately reflect true office costs.

Response: We agree with the commenter on the importance of ensuring accuracy in the pricing of supplies and supply packs. This is why we finalized an update to the pricing of the SA058 supply pack in the CY 2025 final rule to ensure that the price of the full pack matched the price of its individual components. We also finalized the use of a 4-year transition to allow practitioners to adjust to the updated pricing of these supplies (89 FR 97727). We remain open to the submission of additional data regarding the pricing of the SA058 supply pack from interested parties.

Comment: Several commenters agreed with our direct PE refinements to CPT code 52648.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Transurethral Robotic-assisted Resection of Prostate family as proposed.

(13) Cystourethroscopy (CPT code 52443)

At the September 2024 CPT Editorial Panel Meeting, CPT code 0619T (*Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed)* was deleted and replaced with CPT code 52443, which describes an endoscopic procedure for the management of benign prostatic enlargement that entails using both a non-medication-coated and a medication-coated balloon to open the prostatic urethra. CPT code 52443 *(Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a non-drug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed)* was surveyed at the January 2025 AMA RUC meeting.

We proposed the RUC-recommended work RVU of 3.62 for CPT code 52443. For direct PE, we proposed to refine the clinical labor associated with clinical activity CA023 (Monitor patient following procedure/service, no multitasking) to 0 minutes for CPT code 52443. We note that the RUC-recommended a direct crosswalk of most clinical labor times for CPT code 52443 based on reference CPT code 52441 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant*), however, the PE Summary of Recommendations for CPT code 52443 only describes patient monitoring activities done while multi-tasking and does not describe any no-multitasking (1:1) patient monitoring time (clinical activity code CA023) like it was described in the PE SOR for CPT code 52441, reviewed for CY 2020 PFS rulemaking. We therefore proposed to remove this clinical labor time.

We also disagreed with the RUC-recommended 40 minutes for the clinical labor associated with clinical activity CA025 (Clean scope) and proposed to refine CA025 to the standard 30 minutes for a flexible scope. We would like to note that, while the PE SOR for CPT code 52443 did not justify non-standard times for clinical activities CA016 (Prepare, set-up and start IV, initial positioning and monitoring of patient) and CA017 (Sedate/apply anesthesia) of 2 minutes, we did not propose to refine these clinical activity times because there was a robust explanation of these non-standard times in the PE SOR for CPT code 52441, which is a clinically similar endoscopy code requiring positioning and anesthetic activities that warrant the non-standard times for CPT codes 52441 and 52443.

For medical supplies, we proposed to remove the SM022 (sanitizing cloth-wipe (patient)) supply because there are five of these cloth wipes included in the SA058 supply (pack, urology cystoscopy visit).

For equipment times, we proposed to refine the time for the ES031 (scope video system (monitor, processor, digital capture, cart, printer, LED light)) and ES018 (fiberscope, flexible, cystoscopy) equipment items to account for the clinical labor times that should be included in the standard scope systems and scope equipment formulas. We disagree with the RUC-recommended 64 minutes for ES031 and ES018, and we proposed to refine ES031 to 52 minutes and ES018 to 79 minutes in accordance with our standard equipment time formulas for scopes and scope video systems. We proposed all other direct PE inputs for CPT code 52443.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal of the RUC recommended work RVU for CPT code 52443 and the non-standard clinical activity times of 5 minutes for CA016 and CA017, compared to the standard time of 2 minutes.

Response: We appreciate the commenters for their support.

Comment: Many commenters disagreed with our proposed work RVU of 3.62 for CPT code 52443. The commenters claimed that the proposed 3.62 work RVU did not accurately reflect the complexity, time, and expertise required to perform this procedure safely and effectively. Commenters noted that compared to other minimally invasive BPH treatments, balloon dilation requires careful patient selection and precise execution during and immediately after the procedure. For example, the physician must perform a transrectal ultrasound before the procedure to measure the length of the prostate. Commenters claimed that without fair and adequate compensation, many urologists may not be able to provide this treatment option to patients who stand to benefit. Some commenters recommended changing the work RVU to 6.84, which they said better aligns with experience performing the Urolift procedure described by CPT code 52441 and should be used as a direct crosswalk. Other commenters referenced the American Urological Association's (AUA) recommendation of 4.50 work RVUs as a better reflection of the work associated with CPT code 52443. Another commenter disagreed with the work RVU crosswalk from CPT code 52443 to CPT code 52441, stating that it should not have been included on the RSL (reference service list) because the valuation of CPT code 52441 is too low.

Response: We appreciate the commenters for their feedback. However, we continue to believe that our proposed work RVU of 3.62, based on the RUC recommendation, remains the most accurate valuation for CPT code 52443. We received a wide range of possible work RVUs for CPT code 52443. Some commenters recommended work RVUs of 4.50 to as high as 8.50. The majority of commenters recommended work RVUs at or above 7.44, which is more than double the RUC's recommended value, higher than the RUC survey's 75th percentile value, and would break relativity with an anomalously high intensity value. We note that procedures with 30 minutes of intraservice time typically are not valued at a work RVU of 7.44 or higher, and the cystourethroscopy procedure described by CPT code 52443 does not contain the kind of life-threatening patient morbidities which would warrant an outlier intensity valuation.

We wish to clarify for the commenter who claimed that CPT code 52441 should not have been included on the RUC survey for CPT code 52443 that RUC survey respondents did not have to match CPT code 52443 with CPT code 52441; they had the option to match CPT code 52443 to a code with a higher value, if warranted. It is also important to note that the RSL does not dictate what value comes out of the survey or what value gets recommended to CMS, its purpose is to serve as a tool for the individuals filling out the surveys. We remind commenters that CMS has no involvement with the choice of RSL codes or the administration of the RUC's surveys.

Comment: Commenters disagreed with the CMS proposal to refine the clinical labor associated with clinical activity CA023 (Monitor patient following procedure/service, no multitasking) from 5 minutes to 0 minutes. Commenters stated that like the reference code, CPT code 52441, CPT code 52443 is a cystoscopic procedure for the treatment of benign prostatic enlargement. The commenters claimed the typical patient needs to be closely monitored for bleeding, uncontrolled pain and other post-procedural complications in the immediate post-service period when performed in the non-facility setting. Commenters stated that due to the invasive nature of the procedure, typical patients will also need to have their vital signs closely monitored post-service. The commenters recommended 5 additional minutes of non-multi-tasking time to allow clinical staff to best monitor the typically elderly patient having an invasive non-facility procedure to open the prostate.

Response: We appreciate the additional information provided by the commenters regarding the clinical activities associated with CA023. We agree with the commenter that 5 minutes would be more appropriate to closely monitor for bleeding, uncontrolled pain and other post-procedural complications, therefore, we are finalizing the RUC-recommended 5 minutes for CA023 for CPT code 52443.

Comment: Commenters disagreed with the CMS proposal to refine clinical activity CA025 (Clean scope) from the RUC-recommended 40 minutes to the CMS standard of 30 minutes for a flexible scope. They stated that two scopes are used during this procedure, including a two scopes are a transrectal ultrasound probe, therefore the 10 additional minutes was needed for CA025 to clean the second scope, . The commenters stated that the extra 10 minutes is directly tied to the second scope used.

Response: After reviewing the comments, we appreciate the additional information provided about the second scope to support the need for 10 minutes beyond the standard 30 minutes for CA025 for CPT code 52443, and note that 10 minutes of CA025 conforms with our standard cleaning time for a rigid scope, such as a transrectal ultrasound probe. Therefore, we are finalizing 40 minutes total of clinical activity time for CA025 for CPT code 52443 to account for the 30 minutes to clean ES018 and 10 minutes to clean the transrectal ultrasound probe. Upon initial review of the PE SOR and RUC-recommended PE inputs, we note that a second scope was not included in the direct PE for CPT code 52443. Given the additional information provided by the commenter, we assume that EQ250 (ultrasound unit, portable) was used as a substitution because there is not a specific equipment code for a transrectal ultrasound probe (rather than recommending a new equipment type for this code only), therefore, we are finalizing 59 minutes for EQ250 instead of the RUC-recommended 64 minutes to conform with the standard scope equipment formula, which includes the 10 minutes of CA025 attributable to cleaning that rigid scope. We are also finalizing the proposed equipment time of 79 minutes for ES018, which includes the 30 minutes of CA025 attributable to cleaning that flexible scope.

Comment: Commenters disagreed with the removal of the SM021 (sanitizing cloth-wipe (patient)) supply, which they stated was appropriate for this input. They clarified that SM022 refers to sanitizing wipes for surfaces and equipment, noting that four wipes are included to wipe down all surfaces involved in the delivery of patient care, including patient beds, equipment tables, and ultrasound equipment at the conclusion of the procedure. An additional SM021 sanitizing cloth-wipe (patient) is

included instead of the five patient wipes included in the standard cystoscopy pack due to the requirement for this procedure to also place a transrectal ultrasound probe. Notably, the additional wipe is utilized to clean the perirectal area, which is not typically required in standard cystoscopy.

Response: We appreciate the additional information provided by the commenters. In response to public comments, we are not finalizing our proposed refinement and instead are finalizing the RUC-recommended inclusion of a single SM021 supply, due to the use of the transrectal ultrasound probe which requires an additional cloth wipe for the patient.

Comment: Commenters disagreed with the scope video system (ES031) equipment time refinement from 64 minutes to 52 minutes and requested that CMS finalize the RUC recommendation of 64 minutes, which they stated was the appropriate value for this input. They also disagreed with the CMS proposal to refine the equipment times for the flexible cystoscopy fiberscope (ES018) from 64 minutes to 79 minutes for CPT code 52443. A commenter recommended 64 minutes of equipment time for both ES031 and ES018.

Response: After reviewing the comments, we are still not convinced that the information provided would support the need for equipment time to increase from a standard equipment time of 52 minutes to 64 minutes for ES031. Also, based on standard scope equipment time for ES018, we continue to believe that 79 minutes is appropriate, and that the recommended 64 minutes would not be typical for the procedure. The equipment time requested by the commenters was based on the RUC recommendations for this code family, which improperly applied the default equipment time formula by including all of the clinical labor associated with tasks that take place in the preservice portion of the service period. We instead proposed to apply our standard equipment time formula for scopes (ES018) and scope video systems (ES031), which we note resulted in a decrease for the ES031 equipment but an increase for the ES018 equipment. Therefore, for CPT code 52443, we are finalizing our proposed equipment time refinement of 52 minutes for ES031 and equipment time refinement of 79 minutes for ES018.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU and direct PE inputs for CPT code 52443 as proposed with the following exceptions where we are finalizing the following RUC recommended direct PE inputs: 5 minutes for CA023 and the inclusion of a single SM021 supply.

(14) Prostate Biopsy Services (CPT codes 55705, 55706, 55707, 55708, 55709, 55710, 55711, 55712, 55713, 55714, 55715, and 76872)

At the April 2022 Relativity Assessment Workgroup (RAW), prostate biopsy services were reviewed and identified as services performed by the same physician on the same date of service 75 percent of the time or more. As a result of that review, the RAW requested action plans for September 2022 to determine if specific code bundling solutions should occur for CPT codes 55700 (*Biopsy, prostate; needle or punch, single or multiple, any approach*) and CPT code 76872 (*Ultrasound, transrectal;*). The RAW referred that issue to the CPT Editorial Panel for revision of descriptors and for clarity in reporting CPT code 55700 with CPT code 76872. At the May 2024 CPT Editorial Panel meeting, CPT deleted existing CPT code 55700, revised CPT codes 55705 (*Biopsy, prostate; any approach, non-imaging-guided*) and 76872 and added 9 new codes that clarify reporting for prostate biopsies and the imaging procedures that accompany them.

CPT codes 55705, 55706 (*Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance*), 55707 (*Biopsy, prostate, transrectal, ultrasound-guided (ie, sextant), ultrasound-localized*), 55708 (*Biopsy, prostate, transrectal, ultrasound-guided (ie, sextant) with MRI-fusion guidance*), 55709 (*Biopsy, prostate, transperineal, ultrasound-guided (ie, sextant), ultrasound-localized*), 55710 (*Biopsy, prostate, transperineal, ultrasound-guided (ie, sextant) with MRI-fusion guidance*), 55711 (*Biopsy, prostate, transrectal, MRI-ultrasound-fusion guided, targeted lesion(s) only*), 55712 (*Biopsy, prostate, transperineal, MRI-ultrasound-fusion guided, targeted lesion(s) only, first targeted lesion*), 55713 (*Biopsy, prostate, in-bore CT- or MRI-guided (ie, sextant), with biopsy of additional targeted lesion(s), first targeted lesion*), 55714 (*Biopsy, prostate, in-bore CT- or MRI-guided targeted lesion(s) only, first targeted lesion*), and 55715 (*Biopsy, prostate, each additional, MRI-ultrasound fusion or in-bore CT- or MRI-guided targeted lesion (List separately in addition to code for primary procedure)*), and 76872 were surveyed at the September 2024 RUC meeting.

We proposed the RUC-recommended work RVUs for all twelve CPT codes in this family. We proposed a work RVU of 1.93 for CPT code 55705, a work RVU of 4.27 for CPT code 55706, a work RVU of 2.63 for CPT code 55707, a work RVU of 3.39 for CPT code 55708, a work RVU of 3.23 for CPT code 55709, a work RVU of 3.81 for CPT code 55710, a work RVU of 2.61 for CPT code 55711, a

work RVU of 3.10 for CPT code 55712, a work RVU of 4.00 for CPT code 55713, a work RVU of 3.62 for CPT code 55714, a work RVU of 1.05 for CPT code 55715, and a work RVU of 0.67 for CPT code 76872.

We proposed the RUC-recommended direct PE inputs for all of the codes in this family.

We received public comments on prostate biopsy services. The following is a summary of the comments we received and our responses.

Comment: The commenters supported our proposed values for prostate biopsy services and stated that CMS' changes recognized the added complexity and equipment involved in modern prostate cancer diagnosis. Commenters recommended that CMS monitor the use and outcomes of these new procedures and be ready to make refinements.

Response: We appreciate the comments and after consideration of public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Prostate Biopsy Services family as proposed.

(15) Laparoscopic Prostatectomy (CPT codes 55840, 55842, 55845, 55866, 55867, 55868, and 55869)

In April 2023, the RUC's Relativity Assessment Workgroup identified CPT codes 38571 (*Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy*) and 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*) as typically reported together 75 percent or more based on 2021 Medicare claims data and referred them to the CPT Editorial Panel to possibly develop a code bundling solution. In May 2024, the CPT Editorial Panel created two new codes to report laparoscopic prostatectomy with lymph node biopsy(ies) (limited pelvic lymphadenectomy) and with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes, respectively: CPT code 55868 *(Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with lymph node biopsy(ies) (limited pelvic lymphadenectomy)* and 55869 ((*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes*). These new codes were surveyed along with the rest of the family, CPT code 55840 (*Prostatectomy, retropubic radical, with or without nerve sparing*), 55842 (*Prostatectomy, retropubic radical, with or without nerve sparing;*

with lymph :node biopsy(s) (limited pelvic lymphadenectomy)), 55845 (*Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes*), 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*), and 55867 (*Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed*) at the September 2024 RUC meeting.

We proposed the RUC's recommended work RVU for five of the six codes in the Laparoscopic Prostatectomy family. We proposed a work RVU of 21.36 for CPT code 55840, a work RVU of 21.36 for CPT code 55842, a work RVU of 25.18 for CPT code 55845, a work RVU of 22.46 for CPT code 55866, a work RVU of 22.46 for CPT code 55868, and a work RVU of 19.53 for CPT code 55867.

We disagree with the RUC's recommended work RVU of 29.35 for CPT code 55869 and we are instead proposing a work RVU of 27.41 based on a crosswalk to CPT code 50543 (*Laparoscopy, surgical; partial nephrectomy*). The RUC's recommended work RVU of 29.35 is based on a crosswalk to CPT code 27059 (*Radical resection of tumor (for example, sarcoma), soft tissue of pelvis and hip area; 5 cm or greater*). However, CPT code 27059 is a procedure typically performed on an inpatient basis, with nearly 200 minutes of additional total time higher than the surveyed work time for CPT code 55869 (608 minutes as compared with 434 minutes), due to the inclusion of five inpatient office visits in its global period. CPT code 55869 will typically be performed on an outpatient basis and does not contain any inpatient office visits in its global period, which leads us to believe that CPT code 27059 is not the most accurate choice of CPT code for a valuation crosswalk.

Instead, we believe that it is more accurate to propose a work RVU of 27.41 for CPT code 55869 based on the crosswalk to CPT code 50543. This crosswalk code is another type of surgical laparoscopy which more closely matches the intraservice work time (240 minutes against 230 minutes) and total work time (557 minutes against 434 minutes) of CPT code 55869. We also note that the intensity of CPT code 55869 is anomalously high in relation to the rest of this code family at the RUC's recommended work RVU of 29.35, roughly 30-40 percent higher than any of its peer codes. While we agree that CPT code

55869 should have the highest intensity amongst this group of codes, we believe that our proposed work RVU of 27.41 reflects a more accurate intensity relative to the rest of the family.

For the direct PE inputs, we proposed to correct what appears to be an error in the recommendations for CPT code 55867. The RUC-recommended 106 minutes of clinical labor time for the CA039 (Post-operative visits (total time)) activity based on two Level 4 office visits included in the global period for CPT code 55867. However, this CPT code instead contains one Level 3 and one Level 4 office visit which sum to 89 minutes of clinical labor time, not 106 minutes. We proposed to make this correction to the CA039 clinical labor time for CPT code 55867, which also carries over to the equipment time for the power table (EF031) and the surgical light (EF014). We proposed the direct PE inputs as recommended by the RUC in all other cases for this code family.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the proposed work RVU of 27.41 for CPT code 55869 and stated that CMS should instead finalize the RUC-recommended work RVU of 29.35. Commenters stated that CPT code 55869 is significantly more intense than the other services in this code family and the RUC proposed value accurately accounted for this. Commenters stated that the complete extended bilateral pelvic lymph node dissection described by CPT code 55869 adds significant technical complexity and explains the increase in intraservice time for this procedure compared to CPT code 55868. Commenters stated that CPT code 55869 involves not only removal of an organ (prostatectomy) but it also involves a comprehensive lymph node dissection. Commenters also stated that the typical patient population for CPT code 55869 have more advanced prostate cancer compared to patients undergoing other procedures in this code family. Commenters acknowledged that there is a relative dearth of potential crosswalk codes to match CPT code 55869 but still maintained that the RUC's selection of CPT code 27059 was a better crosswalk choice at a work RVU of 29.35.

Response: We disagree with the commenters and continue to believe that our proposed work RVU of 27.41, based on a crosswalk to CPT code 50543, is the most accurate valuation for this service. As we noted in the proposed rule, the RUC-recommended crosswalk (CPT code 27059) has nearly 200 minutes of additional total time higher than the surveyed work time for CPT code 55869 (608 minutes as

compared with 434 minutes). This crosswalk code is also a radical resection of a tumor, which is less of a clinical match than our choice of CPT 50543 (another type of surgical laparoscopy). While we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and that codes do not necessarily need to share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk, we believe that our choice of crosswalk code is a better match both in terms of total time and clinical similarity. We also continue to believe that the intensity of CPT code 55869 is anomalously high in relation to the rest of this code family at the RUC's recommended work RVU of 29.35. While we agree that CPT code 55869 should have the highest intensity amongst this group of codes, we do not agree that the intensity should be roughly 30 to 40 percent higher than any of its peer codes. At our proposed work RVU of 27.41, the intensity of CPT code 55869 is approximately 15 to 20 percent more intense than the other codes in the family which we believe more accurately captures the relationship between these procedures.

Comment: Several commenters concurred with the technical corrections proposed to the direct PE inputs for CPT code 55867 and stated that they appreciated the proposal of the direct practice expense inputs in all other cases for this code family.

Response: We appreciate the support from the commenters for our proposals.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Laparoscopic Prostatectomy family as proposed.

(16) Endovascular Therapy with Imaging (CPT codes 61624, 61626, 75894, and 75898)

In April 2022, the Relativity Assessment Workgroup (RAW) requested action plans to evaluate potential code bundling solutions for the following code pairs: CPT code 61624 (*Transcatheter permanent occlusion or embolization [for example, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation], percutaneous, any method; central nervous system [intracranial, spinal cord]*) and CPT code 75894 (*Transcatheter therapy, embolization, any method, radiological supervision and interpretation*), CPT code 61624 and CPT code 75898 (*Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis*), CPT code 61626 (*Transcatheter permanent occlusion or embolization [that is., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation], percutaneous, any method; non-*

central nervous system, head or neck [extracranial, brachiocephalic branch]) and CPT code 75894, and CPT code 61626 and CPT code 75898. The RUC reviewed these codes during the April 2024 RUC meeting. For CY 2026, the RUC-recommended a work RVU of 20.00 for CPT code 61624, an RVU of 15.31 for CPT code 61626, an RVU of 2.25 for CPT code 75894, and an RVU of 1.85 for CPT code 75898.

We proposed the RUC-recommended work RVU of 2.25 for CPT code 75894 and work RVU of 1.85 for CPT code 75898. However, we have concerns about the survey data due to the significant variations in both work values and intraservice times reported by respondents. These variations can suggest that the proposed RVU values at the 25th percentile may not accurately reflect the actual work involved in performing these services. As a result, we sought public comments regarding the proposed work RVUs for CPT codes 75894 and 75898.

We disagree with the RUC-recommended work RVUs for CPT codes 61624 and 61626. For CPT code 61624, we proposed a work RVU of 17.06 instead of the RUC-recommended 20.00. This proposal is based on a crosswalk to CPT code 49622 (*Repair of parastomal hernia, any approach (that is, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated*). This crosswalk is supported by a range of CPT code 33224 (*Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)*) with a work RVU of 9.04, 135 minutes intraservice time and 204 minutes total time, and CPT code 93590 (*Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve.*) with a work RVU of 21.70, 135 minutes intraservice time and 223 minutes total time. The intraservice time for CPT code 61624 decreased from 232 to 150 minutes, reducing by 82 minutes, and the total time decreased from 362 to 246 minutes, reducing by 116 minutes, which supports a lower RVU. The lower work RVU proposal of 17.06 reflects the significant decreases in both intraservice time and total time for CPT code 61624.

For CPT code 61626, we proposed a work RVU of 13.46 instead of the RUC-recommended work RVU of 15.31. This proposal is based on a crosswalk to CPT code 49594 (*Repair of anterior abdominal hernia[s] [that is, epigastric, incisional, ventral, umbilical, spigelian], any approach [that is, open,*

laparoscopic, robotic], initial, including implantation of mesh or other prosthesis when performed, total length of defect[s]; 3 cm to 10 cm, incarcerated or strangulated). This crosswalk is supported by a range of CPT code 55881 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation*) with a work RVU of 9.80, 120 minutes intraservice time and 202 minutes total time, and CPT code 93580 *(Percutaneous transcatheter closure of congenital interatrial communication (that is, Fontan fenestration, atrial septal defect) with implant*) with a work RVU of 17.97, 120 minutes intraservice time and 210 minutes total time. The intraservice time for CPT code 61626 decreased by 53 minutes, and the total time decreased by 90 minutes, which supports a lower RVU. The lower work RVU proposal of 13.46 reflects the significant decreases in both intraservice time and total time for CPT code 61626.

We also proposed the RUC-recommended direct PE inputs for CPT codes 61624, 75894, and 75898 without refinement. However, we disagree with a few RUC-recommended direct PE inputs for CPT code 61626. We proposed to refine the clinical staff time for the CA011 activity 'Provide education/obtain consent' to the standard of 2 minutes for CPT code 61626. Since no rationale was provided in the PE Summary of Recommendations for extending clinical staff time beyond the standard 2 minutes for the CA011 activity, we believe 2 minutes is more appropriate than the RUC-recommended 5 minutes. We also proposed to change the medical supply quantity of the SD172 (guidewire, cerebral (Bentson)) supply from 1 to 0 because CPT code 61626 describes non-central nervous system procedures, while SD172 is a cerebral guidewire; thus, we believe this supply is not typically used in this service.

Additionally, regarding the clinical labor associated with CA024 (Clean room/equipment by clinical staff), we believe that the RUC's recommendation of 3 minutes for CA024 was not properly accounted for in one of the equipment time formula inputs. Therefore, we proposed an increase of 3 minutes to the equipment time for the angiography room (EL011), which increases from 124 to 127 minutes for this code to incorporate this missing time associated with the CA024 activity. Lastly, for CPT code 61626, the equipment time for the professional PACS workstation (ED053) should be half of the physician preservice time plus the full physician intraservice time. We believe this was an unintended error, and we proposed 152 minutes after rounding up from 151.5 minutes.

Although we proposed the direct PE inputs for CPT codes 75894 and 75898 without refinement, we have concerns over one of the RUC-recommended direct PE inputs, CA021 (Perform procedure/service---NOT directly related to physician work time) as the involvement of additional vascular interventional technologists remains unclear. According to the RUC recommendation, CPT codes 61624 and 61626 should not be reported in conjunction with CPT codes 75894 and 75898. And the RUC's recommendation of 60 minutes of clinical labor time for CPT code 75894 and 45 minutes for CPT code 75898 associated with the CA021 activity did not include an adequate explanation for these activities when CPT codes 75894 and 75898 are performed in the absence of CPT codes 61624 and 61626. Thus, we proposed the direct PE inputs as recommended by the RUC; however, due to the concerns mentioned above, we sought public comments regarding the recommended CA021 clinical labor time of 60 minutes for CPT code 75894 and 45 minutes for CPT code 75898, specifically what intraservice clinical labor time would be typical for these procedures.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposed work RVU of 17.06 for CPT code 61624 and stated that CMS should instead finalize the RUC-recommended work RVU of 20.00. Commenters stated that the RUC's recommendation of the survey median work RVU of 20.00 more accurately described the physician work involved in furnishing this service, as CMS proposed a lower work RVU of 17.06 based on a crosswalk to CPT code 49622. Commenters noted that CPT code 49622 is not an appropriate crosswalk for CPT code 61624 because these two procedures are fundamentally different. Commenters emphasized that CPT code 61624 involves precise catheter-based embolization of cranial or spinal arteries and requires substantially greater physician work, specialized equipment, and highly trained neurointerventional nurses and technologists with expertise in radiation safety and neuro-monitoring. The commenters further noted that the procedure carries higher malpractice risk due to potential severe and permanent neurological injury. In contrast, CPT code 49622 is a straightforward intra-abdominal procedure of lower complexity that relies on standard operating room equipment and does not require similarly specialized staffs. They commenters stated that crosswalking CPT code 61624 to CPT code 49622 significantly undervalues the physician work, practice expense, and malpractice

expense of this complex neurointerventional procedure. A commenter also noted that the survey value for CPT code 61624 is supported by its similarity in intensity to CPT code 61635, which involves vessel stenosis requiring stenting and has an intraservice time of 150 minutes and a total work RVU of 24.28. Many commenters recommended CMS to finalize the RUC-recommended work RVU of 20.00 for CPT code 61624, stating that this value more accurately reflects the physician work and intensity of this complex intracranial procedure.

Response: We appreciate the commenters for the additional information, and we agree with the commenters that crosswalking CPT code 61624 to CPT code 49622 undervalues the physician work, practice expense, and malpractice expense of this complex neurointerventional procedure. Therefore, we are finalizing a work RVU of 20.00 for CPT code 61624.

Comment: Several commenters also disagreed with the CMS proposed work RVU of 13.46 for CPT code 61626 and stated that CMS should instead finalize the RUC-recommended work RVU of 15.31. Commenters stated that the RUC's recommendation of the survey median work RVU of 15.31 more accurately described the physician work involved in furnishing this service. CMS proposed a lower work RVU of 13.46 based on a crosswalk to CPT code 49594 and commenters disagreed with this proposed work RVU; commenters stated that CMS' proposed crosswalk of CPT code 61626 to CPT code 49594 was inappropriate because the work of CPT code 61626 is much more intense than the proposed crosswalk of CPT code 49594. Specifically, commenters stated that CPT code 61626 is a complex neurointerventional embolization involving delicate head and neck vessels, requiring advanced angiographic imaging, microcatheter navigation, and management of catastrophic neurological complication risks, while CPT code 49594 is a standard hernia repair using standard operating room (OR) equipment and has minimal imaging needs. They also stated that CMS relied on inaccurate time estimates rather than the robust physician survey that supports a higher work RVU; therefore, commenters recommended CMS adopt the surveyed valuation and finalize a work RVU of 15.31.

Response: We appreciate the commenters for the additional information they provided. After consideration of public comments, we agree that CPT code 61626, which involves highly specialized neurovascular procedures performed under advanced imaging, entails substantially greater complexity and professional liability than CPT code 49597. The two procedures differ fundamentally in anatomy,

technique, resource requirements, physician work, and risk. Thus, the RUC-recommended work RVU of 15.31 is appropriate and we are finalizing this work RVU for CPT code 61626.

Comment: Regarding CPT codes 75894 and 75898, commenters noted that these services were not surveyed in the Harvard Study and had never been reviewed by the RUC or CMS. Instead, the assigned times were input by CMS over 30 years ago at the inception of the RBRVS using an unknown methodology and, therefore, were not valid for relative comparison to the current survey or to other codes. Commenters emphasized that the current survey provides the most valid and accurate data appropriately capturing the work involved and suggested CMS finalize the recommended values of 2.25 for CPT code 75894 and 1.85 for CPT code 75898.

Response: We appreciate the commenters for the additional information they provided. With regards to codes with older time values, we agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times and it undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our

methodology, we refer readers to our discussion of the subject in the CY 2017 final rule (81 FR 80273 through 80274).

After consideration of public comments, we continue to agree with the commenters that the RUC-recommended values at the 25th percentile accurately reflect the work involved in performing these services. We proposed the work RVU for both CPT code 75894 and CPT code 75898 at the RUC's recommended values, and we are finalizing as such for both codes.

Comment: Several commenters supported CMS' proposal of the recommended direct PE inputs for CPT codes 61624, 75894, and 75898. In addition, a commenter agreed with CMS' correction of the equipment formula inputs by adjusting 3 minutes to the equipment time for the angiography room (EL011), and agreed that the equipment time for the professional PACS workstation (ED053) should be half of the physician preservice time plus the full physician intraservice time leading to 152 minutes.

Response: We appreciate the support of our proposed policies from the commenters.

Comment: For CPT code 61626, commenters emphasized that 5 minutes of clinical staff time for the CA011 activity "Provide education/obtain consent" was necessary, explaining that informed consent for CPT code 61626 requires detailed discussion of complex anatomy, high-risk complications, and procedure-specific considerations, making it far more time-intensive than the standard 2 minutes. On the other hand, another commenter agreed that clinical staff time for the CA011 code should be 2 minutes.

Response: We appreciate the commenters for their feedback. After reviewing the additional information received during the comment period, we agree with commenters that obtaining informed consent for neurovascular embolization procedures of the head and neck (CPT code 61626) requires additional time beyond the standard allocation. As commenters stated, these procedures involve comprehensive discussions of complex anatomy, serious potential risks including stroke, hemorrhage, and cranial nerve injuries, as well as high-stakes clinical conditions that necessitate thorough patient education. Therefore, we are finalizing the RUC-recommended 5 minutes of clinical labor time for the CA011 task for CPT code 61626; we note that this also increases most of the finalized equipment times by an additional 3 minutes.

Comment: Several commenters disagreed with the proposed deletion of the SD172 guidewire, cerebral (Bentson) supply in CPT code 61626. Commenters stated that the SD172 supply should be

retained for patient safety, however if CMS insisted on its removal, then it should be replaced with an additional SD089 (guidewire, hydrophobic) supply.

Response: We disagree with the commenters and continue to believe that use of the SD172 guidewire would not be typical for CPT code 61626. Commenters did not explain why the use of a cerebral guidewire would be typical for a non-central nervous system procedure. However, due to the patient safety concerns identified by the commenters, we will add an additional SD089 guidewire to the direct PE inputs for CPT code 61626. This raises the total quantity of SD089 guidewires to two since CPT code 61626 already included one in its direct PE inputs.

Comment: For CPT codes 75894 and 75898, commenters provided additional information regarding CA021 (Perform procedure/service - NOT directly related to physician work time). They stated that the vascular interventional technologist works closely with the physician to ensure appropriate imaging, adequate contrast to identify and review vessel details, and proper documentation of images. Commenters explained that technologists assist with imaging, supplies, and other tasks not directly associated with physician work time. The RUC stated that the recommended clinical staff times were supported by the RUC process, compelling evidence, and valid survey data for both codes. Commenters believe that the RUC-recommended times of 60 minutes for 75894 and 45 minutes for 75898 for CA021 were appropriate.

Response: We appreciate the additional information provided by the commenters regarding these clinical labor times. We proposed the RUC-recommended direct PE inputs for CPT codes 75894 and 75898, and we agree with commenters that the typical time for clinical activity CA021 (Perform procedure/service —NOT directly related to physician work time) is 60 minutes for CPT code 75894 and 45 minutes for CPT code 75898.

After consideration of the comments, we are finalizing the RUC-recommended work RVUs of 20.00 for CPT code 61624 and 15.31 for CPT code 61626, as well as work RVUs of 2.25 for CPT code 75894 and 1.85 for CPT code 75898. For CPT code 61626, we are finalizing a 5-minute allocation for clinical activity CA011 (providing education/obtaining consent). We are also finalizing the removal of supply item SD172 while adding an additional SD089 supply for CPT code 61626. Finally, we are

finalizing the proposed direct practice expense inputs for CPT codes 75894 and 75898, including 60 and 45 minutes of CA021 clinical staff time, respectively.

(17) Guided High Intensity Focused Ultrasound (CPT code 61715)

In September 2023, the CPT Editorial Panel created a new Category I code to describe magnetic resonance image guided high intensity focused ultrasound (MRgFUS) intracranial ablation for treatment of a severe central tremor that is recalcitrant to other medical treatments for CY 2025 to replace the existing Category III code.

For CY 2025, we finalized the implementation of CPT code 61715 (*Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed*) as a global-only code with direct PE inputs in the facility setting only, as recommended by the RUC. After implementation, an interested party raised concerns about the lack of non-facility pricing for the new CPT code 61715, which would result in an untenable non-facility payment equal to the established facility payment. The interested party expressed concerns about access to the service in the non-facility setting given the facility payment rate and provided information about the appropriateness of the service in the non-facility setting and the payments set by the MACs for the predecessor code. The interested party stated that the predecessor code, CPT code 0398T, was paid $9,750 in the non-facility setting by one MAC, and for CY 2025, CPT code 61715 is paid at $1,180 in the non-facility setting due to being set equal to the facility payment, absent established non-facility PE RVUs. In an effort to temporarily resolve this issue for CY 2025, we implemented PC/TC splits for CPT code 61715, with contractor-pricing for the global and technical components, which would restore MAC discretion in pricing this service, including in the non-facility setting.

For CY 2026, we are seeking comments on non-facility pricing of this service to address the issue permanently. When considering potential crosswalk or reference codes for proposed direct PE inputs in the non-facility setting, we found all codes in the CPT code 615XX, 616XX, 617XX, and 618XX series are only valued in the facility setting and therefore were not tenable crosswalk codes for the non-facility direct PE. Additionally, there are MRI-guidance ultrasound ablation Category III codes that could be commensurate for non-facility direct PE, such as CPT code 0071T (*Focused ultrasound ablation of*

uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue), and the previous predecessor code of CPT code 61715, CPT code 0398T, but they are/were contractor-priced under the PFS and do not have direct PE inputs for consideration.

We considered the prostate tissue MRI-guided ultrasound ablation codes, CPT codes 55881 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation*) and 55882 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed*) as possible references because they are valued in the non-facility setting, but they include very high-cost disposable supplies and equipment that are specific to the CPT codes including SA136 (TULSA-PRO Disposable Kit) and EQ410 (TULSA-PRO TDC Cart), as well as some other direct PE inputs that may not be typical for CPT code 61715.

We also considered partial crosswalks of CPT codes for portions of CPT code 61715, such as CPT codes 77372 (*Radiation* treatment *delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based*), 61800 (*Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)*), 61736 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*), and 61796 (*Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion*), but these codes have similar challenges related to the facility-only pricing and/or direct PE inputs that would not be applicable to or typical for CPT code 61715.

Given these challenges, we sought comments on appropriate non-facility direct PE inputs (clinical labor, disposable supplies, and medical equipment), and/or appropriate crosswalk codes for non-facility direct PE inputs for CPT code 61715. We would also consider a non-facility direct PE RVU crosswalk (in lieu of establishing specific non-facility direct PE inputs) for CPT code 61715 if that PE RVU could be substantiated by commenters. We note that we would not consider the MACs' established payment for the predecessor CPT code 0398T, particularly outlier payment rates, as substantiation for a

PE RVU crosswalk for CPT code 61715 because there was significant variation among the MACs' payment for CPT code 0398T, some of which did not establish payment in the non-facility. Additionally, the established MAC payments do not differentiate between work, PE, and malpractice, making it difficult to establish a reasonable PE RVU for CPT code 61715 based on MAC payment alone. We received a second letter from an interested party stating that the previous non-facility payment rate for CPT code 0398T was $9,750, but we note that this payment rate is a significant outlier payment based on the reported range of payments from the MACs in April 2022. The range of reported payments in the facility setting reported by the MACs in April 2022 for CPT code 0398T was $440.50 to $20,842.19, and $1,554.58 to $2,036.75 when the highest and lowest outliers were removed. Of note, when the outliers were removed from the range, the established payment by the MACs for CPT code 0398T are commensurate with the established national facility pricing of $1,180 for CPT code 61715. In April 2022, only one MAC reported an established non-facility payment of $2,036.75, therefore, we are unable to substantiate the interested parties' statement about a non-facility payment of $9,750 and sought comments on any additional information about the established MAC payments for CPT code 0398T that we could use to consider non-facility pricing for CPT code 61715.The second interested party requested contractor-pricing for CPT code 61715 for CY 2026. We note that, in an effort to temporarily resolve this issue for CY 2025, we implemented the PC/TC splits for CPT code 61715, with contractor-pricing for the global and technical components, to restore MAC discretion when it came to pricing this service. Therefore, for CY 2026, we sought comments on national pricing options in the non-facility setting to address it permanently. We also sought comments in the form of clinical evidence to support the appropriateness of this service in the non-facility setting and the appropriateness of the established PC/TC split for CPT code 61715.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that the proposed reduction in malpractice RVUs from 7.54 to 1.31 for CPT code 61715 represented a dramatic decrease of more than $200 per procedure without clear justification. Commenters stated that this procedure is a complex, high-liability procedure involving stereotactic targeting within the brain under MRI guidance and that a drastic reduction underestimated the

real-world malpractice risk physicians assume. The commenters suggested that CMS to maintain the 2025 malpractice RVUs until sufficient claims data and longer-term safety profiles became available to inform any downward adjustment.

Response: The proposed reduction to the MP RVU for CPT code 61715 was an unanticipated byproduct of the introduction of PC/TC splits that took place during CY 2025. CPT code 61715 was previously valued as a global service without professional and technical component splits; when we introduced these splits, we maintained the current RVUs (including the MP RVU) for the professional component even though it no longer included the technical component portion. When we calculated the proposed CY 2026 valuation for the professional component of CPT code 61715, the MP RVU underwent a significant decrease as the specialties in the claims data reporting only the professional service were different from the specialties that had been reporting the prior global version of the code. This decrease was also magnified as CPT code 61715 is a low volume service where small shifts in the specialty reporting can have an outsized effect on valuation.

To minimize these shifts in the allocation of indirect PE and MP RVUs, we therefore believe it would be more accurate to assign an expected specialty as part of our low volume services list as detailed in section II.B of this final rule. We are finalizing the addition of CPT code 61715 to this list with an expected specialty assignment of Neurosurgery, the most commonly reported specialty for its predecessor CPT code 0398T. We believe that this assignment will result in a more accurate and most stable MP RVU valuation for CPT code 61715.

Comment: Many commenters supported the establishment of non-facility PE RVUs for CPT code 61715 but did not offer specific information about the typical direct PE inputs or appropriate crosswalk codes that we could consider to establish PE RVUs in the non-facility setting. Many commenters expressed concern with non-facility pricing for this service, and stated that the service is not typically performed in the non-facility setting and should only be performed in a tertiary care hospital. Another commenter suggested that we should wait to address payment for CPT code 61715 until the AMA RUC is scheduled to review this code again in 2027. A commenter stated that, based on a detailed simulation of the PE inputs involved with CPT code 61715 in the non-facility setting, the PE RVU should be calculated at 606.74. The commenter stated that this calculation was based on 210 minutes of registered nurse (RN)

labor and 240 minutes of MRI technologist labor, along with a series of additional supply and equipment items in addition to the ones that CMS had finalized in CY 2025 rulemaking. The commenter stated that if CMS declined to adopt this PE RVU, the commenter instead recommended that CMS set non-facility PE RVU for CPT code 61715 via a crosswalk to CPT code 27278 or CPT code 37277.

Response: We appreciate the commenters' feedback regarding non-facility PE RVUs for CPT code 61715. We welcome opportunities to discuss establishing non-facility pricing for this code but remind interested parties that more information is needed regarding typical direct PE inputs and/or more information about appropriate crosswalk codes to price CPT code 61715 in the non-facility setting. We disagree with the commenter that the direct PE inputs and recommended PE RVUs requested by the commenter would be typical for CPT code 61715. The commenter's valuation for this procedure would result in the highest PE RVU on the entire PFS, at approximately $21,000 after applying the proposed conversion factor, while the two suggested crosswalk codes would have a valuation around $13,000. We stated in the proposed rule that a requested $9,750 payment from an interested party appeared to be a major outlier for this service, and the range of reported payments in the facility setting reported by the MACs in April 2022 for predecessor CPT code 0398T was $1,554.58 to $2,036.75 when the highest and lowest outliers were removed. We remind interested parties that valuation under the PFS is based on the typical case which does not support valuations in this range for CPT code 61715.

Comment: Many commenters stated that the proposed efficiency adjustment should not be applied to CPT code 61715, as this code only received its initial valuation in 2025, and standard CMS practice has been to allow 3 years of real-world data before reassessing efficiency gains.

Response: We appreciate the feedback on the proposed efficiency adjustment; we note for the commenters that our discussion of the efficiency adjustment can be found above in section II.E.2.b.

After consideration of the comments, we did not receive enough information about typical non-facility direct PE inputs or reasonable crosswalk codes to finalize non-facility pricing for CPT code 61715 for CY 2026, therefore we are finalizing to maintain the facility pricing and coding structure for CPT code 61715 as proposed. We are also finalizing the addition of this code to the low volume services list with an expected specialty assignment of Neurosurgery as detailed above. We welcome opportunities to

discuss establishing non-facility pricing, but remind interested parties that valuation under the PFS is based on the typical case.

(18) Percutaneous Interlaminar Lumbar Decompression (CPT codes 62330 and 62331)

In September 2024, CPT created two new Category I codes to replace existing Category III code 0275T. CPT codes 62330 (*Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; one insterspace, lumbar)* and 61XX1 (*Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure)* were surveyed for the January 2025 RUC meeting. CPT code 62287 (*Decompression percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar)* was not surveyed as part of the code family due to low utilization (approximately 100 claims in 2023 per the RUC). Specialty societies stated that a code change application requesting the deletion of CPT code 62287 will take place for the 2026 CPT cycle.

We proposed the RUC-recommended work RVUs for both CPT code 62330 (8.00) and CPT code 62331 (4.25) without refinement. We also proposed the RUC-recommended direct PE inputs without refinement for both CPT code 62330 and 62331.

We received comments on our proposals for this code family. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of CMS' proposal of the RUC-recommended work RVUs and direct PE inputs for CPT codes 62330 and 62331. A commenter requested that CMS restore the RVUs for CPT code 62287, stating they believe it was inadvertently removed. Another commenter also encouraged CMS to ensure that the Medicare practitioner community is aware of the availability of these new codes by including them in the annual MLN Matters educational article containing a summary of the final PFS rule.

Response: We appreciate the commenters for their comments. Regarding the comment pertaining to CPT code 62287, we note that we have addressed this as a technical correction under the PE section of this final rule.

After consideration of the public comments, we are finalizing the work RVU values for the Percutaneous Interlaminar Lumbar Decompression code family (CPT codes 62330 and 62331) as proposed. We are also finalizing the direct PE inputs for CPT codes 62330 and 62331 as proposed.

(19) Percutaneous Decompression of Median Nerve (CPT code 64728)

In September 2024, the CPT Editorial Panel created a new CPT code to report percutaneous decompression of the median nerve at the carpal tunnel using ultrasound guidance and a balloon dilation device while transecting the transcarpal ligament: CPT code 64728 (*Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance*). For CY 2026, the RUC-recommended a work RVU of 2.70 for CPT code 64728.

We proposed the RUC-recommended work RVU of 2.70 for CPT code 64728. We would like to note that CPT code 64728 is a new technology procedure, previously reported with an unlisted code, and we received external input suggesting the RVU should be 6.00, which is much higher than the RUC recommendation. However, a review of similarly timed procedures does not support an RVU greater than the RUC recommendation of 2.70. The RUC's valuation for CPT code 64728 is very typical for a procedure code with the same work time values (that is, 20 minutes intraservice time and 57 minutes of total time) and has a typical intensity for this kind of procedure.

We proposed the RUC-recommended direct PE inputs for CPT code 64728 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with CMS' proposal of the RUC-recommended work RVU and direct PE inputs for CPT code 64728.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters stated that the payment associated with the proposed work RVU of 2.70 for CPT code 64728 would not adequately reimburse practitioners for the time, effort, complexity, and expertise that go into providing this service. Commenters stated that given the profound impact

ultrasound guided CTR procedures has on patients, it is crucial to maintain patient access to this minimally invasive approach that gives patients long-term relief, while allowing them to return to their daily activities due to the lack of a need for general or regional anesthesia and minimal recovery time. Commenters stated that this minimally invasive approach does not mean that the procedure itself is low effort and requested that the payment rate for CPT code 64728 be increased to c reflect the time, complexity and intensity of the work involved in performing this procedure.

Response: We appreciate the additional feedback from the commenters, many of whom described their firsthand experience with this procedure. However, we did not receive additional data from these commenters to indicate that CPT code 64728 typically requires additional time or intensity beyond what was provided by the RUC recommendations. As we noted in the proposed rule, a review of similarly timed procedures does not support a work RVU greater than the RUC recommendation of 2.70 and the RUC's valuation for CPT code 64728 is very typical for a procedure code with the same work time values. Therefore, we continue to believe that the proposed work RVU of 2.70 remains the most accurate valuation for CPT code 64728.

Comment: Several commenters stated that the RUC-recommended work RVU was unreliable because it was based in significant part on input from survey respondents with no experience performing this procedure, which skewed the credible survey responses from physicians with substantial real-world experience. Commenters stated that this resulted in a work RVU recommendation that was based on the incorrect assumption that a minimally invasive procedure takes less time and is less intensive to perform, which is not true and is the exact opposite of the situation for CPT code 64728. Commenters stated that using data from survey respondents with no experience performing CPT code 64728 skewed the data and led the RUC to select CPT code 51102 (*Aspiration of bladder, with insertion of suprapubic catheter*) for its valuation crosswalk, which was highly problematic because CPT code 51102 lacks critical elements of the survey procedure. Commenters stated that this was an inaccurate comparison for many reasons, including entirely different anatomy, risks, skills, and time required, but most foundationally, because continuous imaging is an integral part of CPT code 64728 and which is not an element of CPT code 51102.

Response: We disagree with the commenters and continue to believe that the RUC's recommended work RVU of 2.70 is the most accurate valuation for CPT code 64728. The RUC has a long history of using a mixture of targeted and random survey respondents for their survey process, as the targeted survey respondents who have personal experience with the procedure in question tend to overestimate its intensity. Our intention in seeking additional information is not to privilege once source over the other. Prioritizing the results of a targeted survey over the data generated by random respondents would not be methodologically appropriate and could lead to inaccurate valuations.

We also believe that the RUC's use of CPT code 51102 for a valuation crosswalk was an accurate choice for CPT code 64728. CPT code 51102 shares the same intraservice work time of 20 minutes and a highly similar total work time (60 minutes against 57 minutes) when compared with CPT code 64728. While the procedures have significant clinical differences, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. Since the two components of work are time and intensity, and these two codes share highly similar work times along with comparable intensity, we believe that CPT code 51102 is an accurate choice for use as a valuation crosswalk.

Comment: Several commenters pointed to additional data sources separate from the RUC survey conducted for CPT code 64728. Commenters stated that there was additional randomized controlled trial data from the Walter Reed Medical Center which reported a mean intraservice time of 32.2 minutes as compared with 20 minutes from the RUC survey. In addition, commenters stated that an independent physician survey of CPT code 64728 was performed by a third party following the AMA RUC meeting in January 2025. Commenters stated that this independent survey had a robust response rate of 63 percent% with a median intraservice time of 25 minutes and a median total time of 65 minutes. Commenters stated that these times were similar to the targeted respondents from the RUC survey and stated that the participating physicians from the independent survey recommended a work RVU of 6.00 for CPT code 64728. An additional commenter stated that the work RVU for this code should be comparable to CPT codes 64721 at 4.85 or CPT code 29848 at 6.23.

Response: We appreciate the submission of these additional sources of data by the commenters. However, as stated above, we disagree with the commenters and continue to believe that the proposed work RVU of 2.70 remains the most accurate valuation for CPT code 64728. While we are intrigued by the use of randomized controlled trial data from institutions such as the Walter Reed Medical Center, we are skeptical that a mean intraservice time of 32 minutes is typical for CPT code 64728. This value would be higher than the 75th percentile results of the RUC survey, in both the random and targeted categories, as well as higher than the median intraservice time of the independent survey at 25 minutes. The patient population at Walter Reed may not be typical of the broader Medicare community which could explain this disparity in surveyed work time, we would be interested in additional information from interested parties as to the generalizability of data from Walter Reed to the Medicare population. As for the independent survey, we believe that its surveyed times are broadly comparable to the RUC's recommended times, with a finding of 25 minutes of intraservice time (against 20 minutes from the RUC) and 65 minutes of total time (against 57 minutes from the RUC). We believe that this additional data reinforces the notion that CPT code 64728 typically takes approximately 20-25 minutes of intraservice time and 60-65 minutes of total time to be performed. We greatly appreciate having this additional data source and we believe that these additional survey times support and reinforce the time values from the RUC's survey.

Regardless of whether we were to finalize 20 minutes or 25 minutes as the intraservice time for CPT code 64728, in neither case would the work RVU of 6.00 requested by the commenters be an accurate representation of the work associated with performing this procedure. As we noted in the proposed rule, a review of similarly timed procedures does not support a work RVU greater than the RUC recommendation of 2.70 and the RUC's valuation for CPT code 64728 is very typical for a procedure code with the same work time values. Assigning a work RVU of 6.00 would result in an anomalously high intensity for CPT code 64728 as compared to other services on the fee schedule. This valuation would create a major rank order anomaly and would not maintain relativity with other services on the PFS. Similarly, the suggested comparator codes from the commenter (CPT codes 64721 and 29848) are not appropriate choices for valuation crosswalks as they have greatly differing work time values. CPT code 64721 has 171 total minutes of total time while CPT code 29848 has 179 minutes of total time; by

comparison, CPT code 64728 has 57 minutes of total time in the RUC survey and 65 minutes of total time in the independent survey. Since we are tasked by the statute with valuing work based on time and intensity, we do not believe it would be accurate to value CPT code 64728 comparably to other codes with so much greater work time.

We believe that the availability of these kinds of additional data sources can be a great asset in determining the valuation of service. We also believe that the specific case of CPT code 64728 highlights the importance of collecting data as part of a wider family of related codes, which allows for the assessment of relativity between related services. We want to emphasize that although we do not privilege the RUC's recommendations over other data sources, the requested work RVUs from the independent survey do not maintain relativity with other related services on the PFS, which is why we believe that the RUC's recommended work RVU of 2.70 is more accurate in this case. We welcome the submission of additional data regarding the work RVU and work time of CPT code 64728 for use in potential future rulemaking.

Comment: Several commenters stated that the proposed MP RVU for CPT code 64728 was extremely low and out of line with the malpractice expense for other carpal tunnel release procedures. Commenters stated that all three approaches - open, endoscopic, and ultrasound guided - require avoiding injury to the same nerves and nerve branches adjacent to the transverse carpal ligament and involve the same risks. Commenters stated that the MP RVU for CPT code 64728 should be comparable to the MP RVUs for CPT codes 64721 and 29848, and recommended CMS to increase the MP RVU for 64728 to 1.25.

Response: We can clarify for the commenters that our valuation methodology does not attach a specific MP RVU to specific codes in the way that we propose and finalize work RVUs. MP RVUs are instead derived annually based on a formula that primarily utilizes the code's work RVU and the risk factors associated with the specialties that bill the code in the claims data; for more information on the MP RVU methodology, we direct interested parties to Section II.M, Determination of Malpractice Relative Value Units (RVUs). In the specific case of CPT code 64728, this code has a significantly lower proposed work RVU (2.70) as compared with CPT codes 64721 (4.85) and 29848 (6.23), along with

significantly lower total work time as detailed above, which explains why its proposed MP RVU was lower.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 64728 as proposed.

(20) Baroreflex Activation Therapy (CPT codes 64654, 64655, 64656, 64657, 64658, 64659, 93145, and 93146)

Baroreflex activation therapy (BAT) treats heart failure symptoms and resistant hypertension by electrically stimulating carotid baroreceptors within the carotid artery. The BAT modulation system received FDA approval in August 2019, and the CPT Editorial Panel approved conversion from a Category III code set to a Category I code set at the September 2024 CPT Panel meeting through the creation of the following CPT codes: 64654 (*Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (that is, total system), and intraoperative interrogation and programming*), 64655 (*Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only*), 64656 (*Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only*), 64657 (*Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator*), 64658 (*Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator; lead only*), 64659 (*Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator; pulse generator only*), 93146 (*Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (for example, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming, including optimization of tolerated therapeutic level setting*), and 93145 (*Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics*

and programmed therapy values, with interpretation and report (for example, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming). This code family describes the implantation, replacement, revision, removal and interrogation/programming of a BAT modulation system and was surveyed for the January 2025 RUC meeting.

We proposed the RUC's recommended work RVU for seven of the eight codes in the Baroreflex Activation Therapy family. We are proposing a work RVU of 11.00 for CPT code 64654, a work RVU of 11.30 for CPT code 64655, a work RVU of 8.01 for CPT code 64656, a work RVU of 12.13 for CPT code 64657, a work RVU of 8.95 for CPT code 64658, a work RVU of 8.23 for CPT code 64659, and a work RVU of 0.90 for CPT code 93146.

We disagree with the RUC's recommended work RVU of 0.79 for CPT code 93145 and we instead proposed a work RVU of 0.65 based on a crosswalk to CPT code 93279 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber*), which was the top reference code from the survey. We believe that it is more accurate to base the work valuation for CPT code 93145 on this crosswalk to CPT code 93279 due to the close clinical similarity between the two procedures (both of them cardiac device evaluations) which share the same intraservice work time of 10 minutes and the same total work time of 22 minutes.

The RUC recommended the survey 25th percentile work RVU of 0.79 for CPT code 93145, stating that CPT code 93145 has a higher estimated intensity and complexity than the two key reference services (including CPT code 93279). However, we do not agree that CPT code 93145 should be valued at a higher work RVU based on the intensity for a clinically similar device evaluation code like CPT code 93279. The RUC's recommended work RVU of 0.79 results in an intensity for CPT code 93145 which is close to 40 percent higher than the intensity for peer CPT code 93146. We do not believe that this results in an accurate valuation for the two new codes given that CPT code 93145 describes cases where the BAT device is working properly and does not require adjustment, whereas CPT code 93146 describes cases where the BAT device is working properly but requires additional device programming. We believe that

CPT code 93146 should have the higher intensity given the additional device programming required in this code to achieve optimal therapeutic levels for the BAT device. Therefore, we proposed a work RVU of 0.65 for CPT code 93145, which we believe reflects more accurate relativity between CPT code 93145 and CPT code 93146.

We proposed the direct PE inputs as recommended by the RUC for CPT codes 64654-64659. For CPT codes 93145 and 93146, we disagree with the RUC- recommended use of the RN (L051A) clinical labor type. These kinds of device evaluation procedures typically do not make use of RN clinical labor; for example, reference codes 93279 and 93281, which were used as a model for the direct PE inputs of these two new codes, both use a combination of the RN/LPN/MTA blend (L037D) and Medical/Technical Assistant (L026A) clinical labor types. Therefore, we proposed to refine the clinical labor for CPT codes 93145 and 93146 from RN (L051A) to the RN/LPN/MTA blend (L037D); we proposed that the numerical values for each clinical labor input will remain the same, with only the staff type changing from L051A to L037D. We proposed the rest of the RUC-recommended PE inputs without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they appreciated CMS proposing the RUC-recommended work RVU and direct practice expense recommendations for CPT codes 64654, 64655, 64656, 64657, 64658 and 64659.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters disagreed with the proposed work RVU of 0.65 for CPT code 93145 and stated that CMS should instead finalize a work RVU of 0.79 based on the RUC recommendation. Commenters stated that the proposed work RVU of 0.65 relies too heavily on the comparison of measured intensity/complexity between CPT codes 93145 and 93146 and does not accurately account for the survey results. Commenters stated that a direct crosswalk to CPT code 93279 is inappropriate as CPT code 93145 is a new service for patients with chronic heart failure that was placed on the RUC's New Technology list to be re-reviewed in 3 years to ensure correct valuation, patient population and utilization assumptions. Commenters stated that CPT code 93145 has a higher estimated

intensity/complexity than both key reference services and that the RUC recommended work RVU of 0.79 maintains relativity within this code family and across other similar codes.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 0.65 is a more accurate choice for CPT code 93145. We remind commenters that we are tasked by the statute with valuing work based on time and intensity; therefore, we believe that it is entirely appropriate to compare CPT codes 93145 and 93146 based on their respective intensities. Commenters did not explain why CPT code 93145 should be valued close to 40 percent higher than the intensity for peer CPT code 93146 despite being the version of the procedure that does not require additional device programming; we believe that this provides strong evidence that the RUC's recommended work RVU of 0.79 is overvalued. We also note for commenters that we are not ignoring the survey results, as the survey for CPT code 93145 resulted in identical time values as compared with the top reference code, CPT code 93279. Given their identical time values and clinically similar nature of both being device evaluation procedures, we believe that it is more accurate to value CPT codes 93145 and 93279 at the same work RVU of 0.65. We also note that this valuation assigns the same intensity to CPT codes 93145 and 93146, as opposed to the RUC recommendation that anomalously assigns CPT code 93145 significantly higher intensity.

Comment: Several commenters disagreed with the proposal to refine the clinical labor for CPT codes 93145 and 93146 from RN (L051A) to the RN/LPN/MTA blend (L037D). Commenters stated that CPT codes 93145 and 93146 must be performed by registered nurses (RNs) with specialized expertise in advanced heart failure management as the patients receiving BAT are not typical device patients. Commenters stated that evaluating and managing these patients during BAT device interrogation or programming requires a deep understanding of hemodynamics, pharmacology, and device interactions, which are all skills that are well beyond the scope of licensed practical nurses (LPNs) or medical technician assistants (MTAs). Commenters stated that the reprogramming and assessment during BAT follow-up visits are a complex and high-risk process, and it is not uncommon for patients to develop presyncope or syncope while settings are titrated. Commenters stated that the role of clinical staff under CPT codes 93279 and 93281 is fundamentally different and there is minimal independent clinical assessment or medical decision-making required; the difference in skill, responsibility, and clinical risk is

dramatic. The commenters recommended CMS to finalize the original RUC recommendation that included the L051A RN clinical labor time for CPT codes 93145 and 93146.

Response: Based on the additional information provided by the commenters, we agree that there is a difference in the technical skill required for the clinical labor in CPT codes 93145 and 93146 as compared with CPT codes 93279 and 93281, and that the use of the RN clinical labor type would be typical for these procedures. We are therefore not finalizing our proposed refinement to convert the clinical labor for CPT codes 93145 and 93146 from RN (L051A) to the RN/LPN/MTA blend (L037D) and will instead finalize the RUC-recommended RN clinical labor type for all of their clinical labor tasks.

After consideration of the comments, we are finalizing the work RVUs for all of the codes in the Baroreflex Activation Therapy family as proposed. We are also finalizing the direct PE inputs as proposed, with the exception of the change in clinical labor type for CPT codes 93145 and 93146 described above.

(21) Percutaneous Electrical Nerve Field Stimulation (CPT code 64567)

In September 2024, the CPT Editorial Panel created a new CPT code to report percutaneous electrical nerve field stimulation of cranial nerves: CPT code 64567 (*Percutaneous electrical nerve field stimulation, cranial nerves, without implantation*). For CY 2026, the RUC-recommended a work RVU of 1.50 for CPT code 64567.

We proposed the RUC-recommended work RVU of 1.50 for CPT code 64567, and the RUC-recommended direct PE inputs without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they appreciated the CMS proposal of the RUC recommendations for the work RVU, work time, and direct PE inputs for CPT code 64567.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 64567 as proposed.

(22) Laminotomy – Repair of Disc Defect (CPT code 63032)

In September 2024, the CPT Editorial Panel created a new add-on code to report the repair of an annular defect by implantation of a bone anchored annular closure device after a laminotomy (hemilaminectomy): CPT code 63032 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)*). CPT codes 63030 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar*) and 63035 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)*) were identified as codes in the same family as CPT code 63032, but were recently surveyed in 2022 and discussed in the CY 2023 PFS final rule (87 FR 69495 through 64999). The specialty societies stated that the work for these procedures is unchanged and distinct from the work of the new code, and therefore only surveyed CPT code 63032.

For CY 2026, we proposed the RUC-recommended work RVU of 2.50 for CPT code 63032. There are no direct PE inputs for CPT code 63032.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. *Comment:* A commenter recommended that CMS increase the proposed malpractice RVU for CPT code 63032 to 2.19 as opposed to the proposed 0.78. The commenter described the clinical tasks performed in CPT code 63032, involving the implantation of a novel FDA PMA-approved bone-anchored annular closure implant following a laminectomy/discectomy. The commenter stated that considering the additional risk not associated with the primary code (CPT code 63030), which does not involve the implantation of a permanent annular closure implant, the MP RVU should be increased for CPT code 63032.

Response: We would like to clarify that our valuation methodology does not attach a specific MP RVU to specific codes in the way that we propose and finalize work RVUs. MP RVUs are instead derived annually based on a formula that primarily utilizes the code's work RVU and the risk factors associated

with the specialties that bill the code in the claims data; for more information on the MP RVU methodology, we direct interested parties to section II.M, Determination of Malpractice Relative Value Units (RVUs). In the specific case of CPT code 63032, this code has a significantly lower work RVU (2.50 compared to 12.00) and total work time (21 minutes compared to 305 minutes) as compared with CPT code 63030 which explains why its MP RVU is lower than the base code that it is billed with.

After consideration of the comments, we are finalizing the work RVU of 2.50 for CPT code 63032 as proposed. We proposed and we are finalizing no direct PE inputs for this code.

(23) Cerebral Perfusion & CT Angiography-Head & Neck (CPT codes 70496, 70498, 70471, 70472, and 70473).

In May 2024, the CPT Editorial Panel created three new codes for cerebral perfusion and CT angiography of the head and neck: CPT code 70471 (*Computed tomographic angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing*), CPT code 70472 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)*), and 70473 (*Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy*). Codes 70471, 70472, and 70473 were surveyed for the September 2024 RUC meeting, along with the existing standalone codes for CTA head and CTA neck in this code family: CPT code 70496 (*Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing*) and CPT code 70498 (*Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing*).

We proposed the RUC-recommended work RVU of 2.50 for CPT code 70471, the work RVU of 0.77 for CPT code 70472, the work RVU of 1.00 for CPT code 70473, and the work RVU of 1.75 for both CPT codes 70496 and 70498.

We proposed the RUC-recommended direct PE inputs for CPT codes 70471, 70472, 70473, 70496, and 70498 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they agreed with the proposal of the RUC-recommended work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Cerebral Perfusion & CT Angiography-Head & Neck family as proposed.

(24) Coronary Atherosclerotic Plaque Assessment (CPT code 75577)

In September 2024, the CPT Editorial Panel created new Category I CPT code 75577 (*Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified health care professional*) and deleted the four existing Category III CPT codes associated with coronary atherosclerotic plaque assessment.

We proposed the RUC-recommended work RVU of 0.85 for CPT code 75577. For the direct PE inputs, these recommendations also include a new supply item, Plaque Characterization Analysis Software, that lists a per-patient fee of $1500 for the plaque data analysis summary generated by the vendor. This RUC-recommended supply item accounts for the overwhelming majority of this CPT code's PE valuation. We continue to have concerns that software analysis fees are not well accounted for in our direct PE methodology, as discussed for CPT code 75580 (*Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*) in our CY 2024 final rule (88 FR 78901); however, we recognize that the analysis represents a significant part of the resource costs associated with this procedure.

Similar to our previously finalized policy for CPT code 75580, we are therefore proposing to identify a crosswalk code for CPT code 75577 based on the OPPS assignment for the current coding under which this service is paid, Category III CPT code 0625T (*Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data*

from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography). We proposed to crosswalk the PE RVU for CPT code 75577 to the PE RVU for CPT code 77373 (*Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions*), which is a PE-only code with no work RVU and which closely approximates the OPPS assignment previously employed by Category III CPT code 0625T. As we have previously stated in rulemaking, we believe that crosswalking the PE RVU for CPT code 75577 to a code with similar resource costs (CPT code 77373) allows CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 75577, which would not typically be considered direct PE under our current methodology (86 FR 65038 and 65039).

We received public comments on coronary atherosclerotic plaque assessment services. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed work RVU and use of a valuation crosswalk to CPT code 77373 to determine the PE RVU for CPT code 75577. Commenters also requested that this CPT code be excluded from the proposed efficiency adjustment policy.

Response: We appreciate the commenters for their support. We acknowledge commenters' request to exclude CPT code 75577 from our proposed efficiency adjustment policy and we refer readers to that discussion in the valuation of specific codes section in this rule for more information regarding CPT codes excluded from the efficiency adjustment policy.

Comment: A commenter expressed concern regarding the new supply item, Plaque Characterization Analysis Software, that lists a per-patient fee of $1500 for the plaque data analysis summary generated by the vendor. They stated that this is a high-cost supply item and expressed concerns that a crosswalk is an ad hoc approach that could lead to instability if it is changed in future years.

Response: We acknowledge the commenter's broader policy concerns regarding the supply-item, Plaque Characterization Analysis Software, and we refer readers to the comment solicitation regarding high-cost supply items contained within the discussion for the Lower Extremity Revascularization code family for additional information on this topic, as well as our prior discussion in the CY 2011 PFS final

rule with comment period (75 FR 73251) where we discuss broader challenges regarding our ability to price high cost disposable items.

After consideration of the comments, we are finalizing our policies for CPT code 75577 as proposed.

(25) Use of the Relationship Between OPPS APC Relative Weights to Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT codes 77387, 77402, 77407, 77412, and 77417), Superficial Radiation Treatment (CPT codes 77X05, 77X07, 77X08, and 77X09), and Proton Beam Treatment Delivery (CPT codes 77520, 77522, 77523, and 77525)

A. Background

We typically establish two separate PE RVUs for services that can be furnished in either a non-facility setting, such as a physician's office, or a facility setting, such as a hospital. The non-facility PE RVUs reflects all the direct and indirect practice expenses involved in furnishing a particular service when the entire service is furnished in a non-facility setting. The facility PE RVUs reflects the direct and indirect practice expenses associated with furnishing a particular service in a setting such as a hospital, where those facilities incur a portion of the costs and receive a separate Medicare payment for the service. The types of costs covered by the facility fee are comparable to the PE costs incurred by physicians in non-facility settings, namely direct and indirect costs. For certain services, such as radiation treatment delivery services, the coding itself reflects differing types of resources associated with furnishing the service—from coding describing the technical aspects of the treatment delivery only, which do not include any physician work, to codes that describe both the physician work, and the technical resources associated with that work. The former services are valued through information on the direct practice expenses, whereas the latter are valued through the resource costs associated with the physician work and any applicable direct practice expenses.

When services are furnished in the facility setting, such as a Hospital Outpatient Department (HOPD) or an Ambulatory Surgical Center (ASC), the total combined Medicare payment (made to the facility and the professional) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other non-facility setting. This payment difference is largely based on differences in statutory provisions that specify how payment amounts are determined under the PFS and

under facility payment systems, like the Hospital Outpatient Prospective Payment System (OPPS). CMS has received feedback from interested parties that the difference reflects the greater costs that facilities incur than those incurred by practitioners furnishing services in offices and other non-facility settings. For example, interested parties have indicated that hospitals incur higher overhead costs because they maintain the capability to furnish services 24 hours a day and 7 days per week, generally furnish services to higher acuity patients than those who receive services in physicians' offices, and have additional legal obligations such as complying with the Emergency Medical Treatment and Labor Act (EMTALA). Additionally, hospitals incur expenses to meet conditions of participation and ASCs incur expenses to meet conditions for coverage in order to participate in Medicare; many of these conditions are not applicable in non-facility settings.

While we receive recommendations from the RUC that include information on resource costs, this information relies heavily on the voluntary submission of information by individuals furnishing the service. Furthermore, in the case of certain direct costs, such as the price of high-cost disposable supplies and expensive capital equipment, even voluntary information has been very difficult to obtain or validate. Such incomplete, small sample, potentially biased or inaccurate resource input costs may distort our valuation of the non-facility PE RVUs used in calculating PFS payment rates for individual services. As MedPAC noted in their comment to the CY 2011 PFS proposed rule, “using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers may not result in objective and accurate prices because each group has a financial stake in the process”. We have repeatedly stated, such as in the CY 2018 final rule, that “we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs” (82 FR 52998). In addition to the difficulty we face in obtaining accurate information about some of the direct PE inputs, the data used in the PFS PE methodology can often be outdated. Although we received updated PPI survey information from the AMA, we did not propose to utilize this new data in our practice expense methodology due to concerns we identified in section II.B. of this final rule. We refer readers there for further discussion.

Under the PFS, we strive to maintain relativity in a variety of ways. For example, we typically review the work RVUs, physician time, and direct PE inputs for all codes within families of codes. We

also routinely compare work RVUs across services with similar clinical characteristics, global periods, etc. For direct PE inputs, we routinely make standardized assumptions regarding the typical involvement of clinical staff or use of medical equipment based on the kind of service being furnished.

However, we also recognize that the utility of using the exact same methodologies to establish and maintain appropriate relativity under the PFS can be especially limited for services that are difficult to compare to other PFS services. Radiation treatment delivery services are a clear example of this dynamic. Generally, the PFS practice expense methodology serves the purpose of using direct cost and professional work data to assign relative value units to services. In establishing non-facility PE RVUs, these settings include physician offices for a range of kinds of care and specialties as well as independent clinics/suppliers. However, the costs for furnishing radiation treatment delivery services in non-facility settings (that is, freestanding radiation therapy centers) include capital-intensive and specialized resources that are difficult to compare to the kinds of resources involved in furnishing most other kinds of services in other non-facility settings. For example, the sum of the current prices for the equipment inputs used in the PE calculations for radiation treatment delivery services (that is, $3,000,966 for ER089 (IMRT accelerator) and $773,104 for ER056 (radiation treatment vault)) is well over twice the price of the next most expensive piece of equipment ($1,559,013 for EL008 (room, MR) used in furnishing other types of services in other non-facility settings. Furthermore, other inputs for capital equipment over $1 million are utilized in a wide array of services for multiple specialties, while the equipment inputs for radiation treatment delivery services are more specialized in that they are used in a small number of services and predominantly in radiation oncology. We have long had difficulty understanding how best to characterize the costs associated with architectural infrastructure needs prompted by the use of linear accelerators. In the CY 2016 PFS final rule (80 FR 70953), we stated that we believe at least some portions of the costs associated with the radiation treatment vault construction are indirect PE under the established methodology. We most recently noted this difficulty in CY 2021 PFS rulemaking when addressing our inability to use the recommended direct PE inputs for proton beam therapy services (85 FR 84625). We described difficulty using invoices provided, given that they did not separately identify the direct PE inputs (that is, cost of the equipment) from that of the infrastructure needs surrounding the equipment. For the CY 2016 PFS final rule (80 FR 70954), technical PFS rate setting concerns related to how costs

were allocated to different codes based on presumptions about costs of image guidance, prompted CMS to maintain the HCPCS G-codes under the PFS in use for reporting radiation treatment delivery services instead of newly introduced CPT codes. (These HCPCS G codes, which mirrored the coding structure prior to the newly introduced CPT codes, were developed for CY 2015 PFS rulemaking to allow CMS to include the changes to radiation treatment delivery services in the CY 2016 PFS proposed rule). At that time, CMS adopted the new CPT codes for use under the OPPS, where payment calculations did not suffer from the same problems. Since that time, outpatient radiation therapy services have been reported to Medicare using two different sets of HCPCS codes, depending on whether the services are provided in a HOPD or in a non-facility setting paid under the PFS.

For CY 2026, the CPT Editorial Panel has again revised the codes describing radiation treatment delivery services. This presents an opportunity both to consider adopting CPT codes under the PFS and to re-examine how to best assign relative value units to radiation treatment delivery and superficial radiation treatment delivery services under the PFS. If we were to utilize the RUC-recommended direct PE inputs and new RUC PE survey data to value the new, newly payable, and revised codes in these code families, valuation, and ultimately payment, for these services would be subject to the additional volatility associated with small sample surveys, the unique dynamic of capital-intensive costs, and voluntarily submitted invoice data.

We considered the RUC recommended PE inputs for the new, and revised codes listed above in the context of the concerns we outlined above. Specifically, we considered how PE is allocated for under the standard methodologies and noted that radiation treatment delivery and superficial radiation treatment services require long-term capital and infrastructure investments more like facility costs than most other services paid under the PFS. Therefore, we have determined that identifying an alternative data source that is more routinely updated and standardized would improve the accuracy of valuation for these services.

One alternative data source that we have examined is the use of OPPS cost data to develop PE RVUs. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. Under contract with CMS, RAND

Corporation (''RAND'') examined the feasibility of using OPPS cost data in developing PE RVUs[66],[67]. RAND noted that "if OPPS-based costs were used to construct total PE RVUs, the valuation process would also be streamlined by using a single data source, thereby eliminating the valuation complexities posed by having separate direct and indirect cost RVU pools." RAND identified a number of methodological issues that would need to be resolved to utilize OPPS cost data for all PFS services but found that the potential benefits justified investments to further develop this option. RAND noted that using OPPS data "might not be appropriate for the entirety of services in the MPFS and the advisability of using OPPS data should be evaluated by categories of costs and/or services." Considering that the resources involved in furnishing radiation treatment delivery and superficial radiation treatment delivery services seem to be primarily driven by capital costs that aren't as likely to vary greatly between facilities like hospitals and free standing centers, and because the billing codes for the services (both old and new) are already stratified into professional and technical services, these services have obvious characteristics that make use of OPPS data particularly appropriate. Additionally, the use of routinely updated, auditable, and standardized cost data from hospital cost reports that is currently used in setting rates under the OPPS offers the possibility of long-term stable rates that many interested parties have long sought and that may be helpful in maintaining access to care for capital-intensive services. Consequently, we believe that using OPPS data in setting the relative rates for these kinds of services represents the best source for improved valuation of practice expense in free-standing radiation centers.

We have long noted that data obtained from hospital cost reports is regularly updated, auditable, and required to adhere to national standards for reporting. For example, in the CY 2015 PFS final rule (79 FR 67569), we noted that "routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our usual methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year".

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[66] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. https://www.rand.org/pubs/research_reports/*RR2166.html*.

[67] Burgette, Lane F., Joachim O. Hero, Jodi L. Liu, Catherine C. Cohen, Barbara O. Wynn, Katie Merrell, et al. Practice Expense Data Collection and Methodology.'' RAND Corporation, November 1, 2021. *https://www.rand.org/pubs/research_reports/RRA1181-1.html.*

Under OPPS, services are grouped based on clinical characteristics and resource costs into Ambulatory Payment Classifications (APCs). The OPPS methodology utilizes charges from claims data and cost-to-charge ratios developed from cost report data to establish the geometric mean costs for each APC. APC payments are in turn based on the geometric mean costs associated with the services within the APC.

While the costs involved in furnishing technical services in the facility setting could generally be expected to be greater than or equal to those of providing the same service in the non-facility setting, we believe that the *relationship* of the costs of services within a code family under the PFS would likely mirror the relationship of those costs of services under the OPPS. (The Ambulatory Surgical Center (ASC) fee schedule, which relies on OPPS relative weights multiplied by an ASC conversion factor, is an example of using the same underlying data to establish relative values in two payment systems while continuing to recognize differences in cost structure between settings). For example, if "service A" is twice as costly under the OPPS as "service B", it is reasonable to assume that the resource costs of "service A" are twice as costly as "service B" under the PFS. We would expect that the relationship between the resources involved in furnishing services within the same code family under the OPPS would be similar under the PFS. Given that the APC is the payment unit under the OPPS, we believe that applying the relationship of the APC relative weights to the codes within the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families is the most accurate and transparent mechanism to translate the relationship of the cost data under the OPPS to the PFS. This approach would help to mitigate volatility in relativity among services that would be attributable to small sample surveys, voluntarily submitted invoice data, or PE allocation methodologies that are not designed primarily for capital-intensive costs in architecture and medical equipment as costly as linear accelerators. Therefore, we proposed to use this relationship between the relative weights of the OPPS APCs to which the codes in these families are assigned to value the PE portion of the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families. We proposed to use the CY 2026 proposed OPPS APC relative weights and to update these in the final rule based on the updated OPPS APC relative weights. The OPPS APC relative weights can be found in "Addendum B" under "OPPS Addenda" under

the most recent proposed or final rule listed at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*.

We also proposed to value the MP RVUs for the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families with our usual methodology for PE-only services.

While we believe that the relationship between services within the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families are well approximated by the relationship between those services under the OPPS, we recognize that the RVUs for these groups of services must reflect the resources involved in furnishing services relative to other services paid under the PFS. As such, the proposed PE RVUs for the Radiation Oncology Treatment Delivery and Superficial Radiation Treatment code families, which are based on the relationship of the relative weights of the OPPS APCs to which these codes are assigned, were calculated using the portion of total PE and MP RVUs accounted for by the volume and PE RVUs of these families as they existed in CY 2025. In other words, we calculated the RVUs for these codes so that the overall PE and MP RVUs for these services represent the same share of total PE and MP RVUs in CY 2025 and CY 2026.

Under the PE methodology, the allocation of indirect PE for a given family of services impacts the allocation of indirect PE for other services furnished by the specialties that furnish that family of services ("relevant specialties"). This results from specialty-specific calculations that occur in steps 12 through 15, described in section II.B. of this final rule, that are impacted by the size of the pool of indirect allocators (that is, work RVUs and direct costs) for each specialty. Since the codes in these families have historically contained direct PE inputs and have historically been allocated indirect PE RVUs using the usual methodology, the proposed PE RVUs for CY 2026 have been calculated in a manner that maintains the same effect on the indirect allocation for other services had the PE RVUs been calculated under the usual methodology. In other words, in calculating the proposed PE RVUs for CY 2026, we approximated the direct costs for these services and allocated indirect PE RVUs per the standard methodology to both arrive at PE RVUs based on the proposal described above and also maintain relativity with the PE RVUs across the fee schedule. We have included those approximate direct costs in the downloads section of our website to facilitate transparency. We note that the direct PE input public use file does not include these proxy inputs since they only serve the purpose of stabilizing the PE allocated to other services. We

sought comments on this aspect of the methodology in particular, especially given our interest in transparency in rate setting.

We believe that this proposal will improve the accuracy of the relative values established for these services and prevent reliance on irregularly updated information for establishing and maintaining payment for these services under the PFS. Additionally, we believe that the alignment of coding, underlying cost data and billing units between settings paid under the PFS and OPPS will have additional salutary effects, especially in price transparency for patients and payers.

We sought comments on our proposal to use the relative relationship between the proposed OPPS APC relative weights to establish the PE RVUs for these code families.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal, stating that utilizing OPPS data will facilitate long-term payment stability, mitigate payment volatility and is better suited for capital-intensive radiation oncology services, noting that the current PE methodology was not designed for expensive equipment like linear accelerators.

Other commenters opposed our proposal. Some commenters were fundamentally opposed to using OPPS data for PFS rate-setting, stating that hospital charge data lacks the granularity of physician practice costs and stating the approach violates Balanced Budget Act of 1997 (BBA) requirements for cost accounting principles. A commenter emphasized that the current methodology's "bottom-up" granular approach is preferable to hospital "averaging" systems. Commenters questioned whether hospital cost data accurately reflects physician practice costs given concerns about charge compression, which occurs when hospitals a lower markup to relatively high cost items and a higher markup to relatively lower cost items. Commenters stated that these hospital charging practices may undervalue high-cost services. Commenters also expressed concern that hospitals may not be accurately accounting for Intensity modulated radiation treatment delivery(IMRT) costs, with some requesting that hospitals directly allocate radiation oncology equipment costs to appropriate cost centers. Some commenters stated that APC groupings result in a loss of granularity due to the averaging of multiple unrelated procedures.

Response: We appreciate commenters support for our proposal. We agree that the use of OPPS APC relative weights to establish the relative relationship of PE RVUs for radiation treatment delivery services is more suited for capital-intensive services. We disagree with commenters who stated that CMS does not have the authority to utilize OPPS data in PFS ratesetting. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. We acknowledge commenters' concerns about charge compression and the averaging nature of the OPPS payment system. However, we believe the relationship between the APC relative weights reasonably approximates the relationship between the resource costs required to furnish these services under the PFS.

Comment: Many commenters expressed concerns about payment reduction impacts, citing estimated reductions ranging from 9 percent to 52.5 percent for various combinations of services. Some commenters stated that the economic and policy implications of these proposed changes extend far beyond immediate payment adjustments, with significant market consolidation risks including financial strain that may force more independent practices into hospital systems. Commenters stated that reduced payments could result in migration to hospital outpatient departments, resulting in reduced competition and increased Medicare expenditures. Commenters expressed concern that reduced payments could potentially limit adoption of advanced treatment technologies, risk compromising access to IMRT and other advanced modalities, and result in workforce instability that could affect treatment quality and safety.

Response: As we described in the proposed rule, we calculated the RVUs for these codes so that the overall PE and MP RVUs for these services represent the same share of total PE and MP RVUs in CY 2025 and CY 2026. Therefore, while the RVUs for certain combinations of services may differ between CY 2025 and CY 2026, in aggregate, the total PE and MP RVUs for these services were calculated to be similar.

Comment: Some commenters requested that CMS delay implementation to allow more robust data collection from freestanding practices. These commenters suggested this data could include practice-specific surveys to gather more comprehensive cost data from freestanding centers, better capture actual equipment usage and depreciation, and more accurately assess indirect practice expenses.

Response: Because we believe that using the OPPS data in setting the relative rates for these kinds of services represents the best source for improved valuation, we do not believe it is prudent to delay implementation of this proposal. However, we remain open to additional information, such as that cited by commenters, that could help us inform future proposals that address these services.

Comment: Some commenters expressed concern that image guidance costs will no longer be recognized. A commenter expressed concern that not all RVUs were redistributed from deleted codes.

Response: As we stated in the proposed rule, the valuation of the PE RVUs for the newly valued CPT codes includes a redistribution of the PE RVUs from the newly bundled services to the other services in that family. Therefore, while image guidance costs will not be separately payable, the payment for the treatment delivery services includes the resource costs associated with furnishing the image guidance services. Regarding the concern that not all RVUs were redistributed from deleted codes, we are confirming that we are including the volume for all of these services in calculating the share of PE and MP RVUs that these services represented in CY 2025.

Comment: Several commenters stated that CMS did not demonstrate what the PE RVUs would have been had it applied the standard PE methodology using the RUC's recommended direct PE inputs. Commenters stated that without this comparison, interested parties could not meaningfully assess the impact of CMS' proposal to base PE RVUs on OPPS-derived relative cost data which undermined transparency in policymaking.

Response: We acknowledge the concerns of the commenters and agree that additional information regarding alternatives considered would have assisted in providing opportunities for feedback from interested parties. However, due to the concerns that we outlined in the proposed rule, we believe that the volatility associated with small sample surveys, the unique dynamic of capital-intensive costs, and voluntarily submitted invoice data all contributed to making these services unusually difficult to value through our traditional PE methodology. The coding for these services has also proven to be problematic over the past decade, which previously led to the creation of 17 HCPCS G-codes as discussed below. Any discussion of alternatives considered would have required also publishing valuations for the maintenance of the G-code set, since maintaining these codes would have represented the continuation of current policy. Therefore, we chose to focus on our proposed valuation based on the use of OPPS cost data due to

our stated belief that it would be methodologically more accurate for these services. Given the long-standing problems associated with using bottom-up input recommendations for these kinds of services, the inherent alternative to our proposal, of course, would be to maintain the existing set of G-codes and inputs for use under the PFS for CY 2026.

Comment: A commenter recommended that once utilization data becomes available, CMS use the geometric mean of each CPT code rather than APC payment rates to establish the relativity of the PE RVUs.

Response: We may consider this commenter's request in future rulemaking.

B. Radiation Oncology Treatment Delivery (CPT codes 77387, 77402, 77407, 77412, and 77417)

At the September 2024 CPT Editorial Panel meeting, the Panel approved the revision of CPT codes 77402, 77407 and 77412 to establish a technique -agnostic family of codes and bundle imaging into the three CPT codes, and the deletion of CPT codes 77385, 77386 and 77014. The related guidelines and tables were all updated to reflect the consolidated services for radiation oncology treatment delivery. These services were subsequently reviewed by the RUC and a valuation recommendation was submitted to CMS for inclusion in CY 2026 rulemaking. Please see Table A-E7 for the current and CY 2026 code descriptors (where applicable) for the CPT codes in this family.

TABLE A-E7: COMPARISON BETWEEN CURRENT AND CY 2026 LONG DESCRIPTORS

HCPCS	Current Long Descriptor	CY 2026 Long Descriptor
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day	Deleted
77402	Radiation treatment delivery, >=1 MeV; simple	Radiation treatment delivery; Level 1 (for example, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed
77407	Radiation treatment delivery, >=1 MeV; intermediate	Radiation treatment delivery; Level 2, single isocenter (for example, 3D or IMRT), photons, including imaging guidance, when performed
77412	Radiation treatment delivery, >=1 MeV; complex	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (for example, 2D, 3D, or IMRT) OR a single isocenter photon therapy (for example, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple	Deleted
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex	Deleted
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed	
77014	Computed tomography guidance for placement of radiation therapy fields	Deleted
77417	Therapeutic radiology port image(s)	

Although these CPT codes were established for CY 2015, CMS has not used them for payment under the PFS. In October 2013, the CPT Editorial Panel created CPT codes 77402, 77407, 77412, 77385, 77386 and 77387, which were reviewed at the January 2014 RUC meeting for CY 2015. Previously, radiation treatment delivery had been reported with 17 CPT codes. CMS identified concerns with the packaging of Image-guided Radiation Therapy (IGRT) into some of the delivery codes in the family and not others. As a result, CMS created 17 HCPCS G-codes, to mirror the existing codes (at the time), maintained CPT code 77014, and established values that linked directly to the existing values/inputs for the PFS. Table A-E8 includes the HCPCS G-codes and their long descriptors.

TABLE A-E8: HCPCS G-CODES FOR RADIATION TREATMENT DELIVERY

HCPCS	Long Descriptor
G6001	Ultrasonic guidance for placement of radiation therapy fields
G6002	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy

HCPCS	Long Descriptor
G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev
G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6-10 mev
G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11-19 mev
G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20 mev or greater
G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: up to 5 mev
G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 6-10 mev
G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 11-19 mev
G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 20 mev or greater
G6011	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 mev
G6012	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10 mev
G6013	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19 mev
G6014	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 mev or greater
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg,3d positional tracking, gating, 3d surface tracking), each fraction of treatment

Over the past several years, the Radiation Oncology community met with CMS and CMMI to address the concerns identified by CMS in the 2015 code set as well as the possibility of creating an episode-based alternative payment approach for radiation therapy services. The G-codes were identified in a Relativity Assessment Workgroup (RAW) screen (CMS/Other source with 2019 estimated Medicare utilization over 20,000). The RAW did not agree with the specialty societies' request to maintain the current valuation because the inputs for these services were last reviewed in 2014, CMS did not accept the RUC recommendations, and the inputs may not represent the services as they are currently performed. As a result, the CPT Editorial Panel reviewed the radiation oncology delivery treatment family at the September 2024 CPT meeting and established a technique-agnostic family of codes and bundled imaging into all three services. The Panel approved the revision of CPT codes 77402, 77407 and 77412 and the deletion of 77385, 77386 and 77014. The specialty societies have also requested that CMS delete the related G-codes, G6001 through G6017. As stated previously, we have not recognized the radiation treatment delivery CPT codes for payment under PFS and have instead used the G-codes to describe these

services, based primarily on concerns related to how the conventional practice expense methodology applies to these services. For CY 2026, we are proposing to delete the 17 G-codes and recognize the newly revised CPT codes for payment under the PFS, in conjunction with our proposal to utilize OPPS cost data to establish PE RVUs, as previously described.

We proposed the RUC-recommended work RVU of 0.70 for the single code in the family that has a physician work component, CPT code 77387.

We proposed to utilize the relationship between the proposed OPPS APC relative weights for APCs 5621, 5622, and 5623 to inform the valuation of PE-only CPT codes 77402, 77407, and 77412 when paid under the PFS. As described above, we believe that the relationship between the OPPS APC relative weights more accurately reflects the relative resource costs associated with furnishing these services.

To facilitate the use of the relationship of the OPPS APC relative weights to establish PE RVUs for radiation treatment delivery services, we believe it is important to standardize the billing units and bundling rules between the settings. That is, services in this code family that describe technical costs and are not separately payable under the OPPS will not be separately payable under the PFS, because the associated costs are incorporated into the costs for separately paid codes. As a result, the proposed PE RVUs for the services in this code family, which are developed based on the relationship of the APC relative weights to which services in this family are assigned, include a redistribution of the PE RVUs from the newly bundled services to the other services in that family, as described in this section.

In an effort to align the relationship between the PFS payment for this code family with the OPPS payment, we are proposing to assign Procedure Status "B" to the technical component of CPT code 77387 to maintain consistency with OPPS payment for this code, which is packaged into payment for the treatment delivery codes, CPT codes 77402, 77407, and 77412, and therefore is not separately payable under the OPPS. As described in section II.B. of this final rule, typically, when services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. In the case of CPT code 77387, we proposed that the PE and total RVU for the global service will equal the PE and total RVU for the professional component only because the technical component is not separately payable under the PFS since the relative resources are included in the valuation of another

code (treatment delivery). We proposed to display CPT code 77387 in Addendum B with the professional and technical components, where the technical component has non-payable Procedure Status "B," as well as the global service equal to the payable professional component, We also sought comment on strategies to mitigate billing confusion that could result from this relatively novel circumstance where the technical component of a service is bundled but the professional component is separately reported. Specifically, we are seeking comments on whether displaying the global service equal to the professional component is problematic, and if it would be preferable to eliminate the global code and display only the professional and technical components in Addendum B.

Similarly, for PE-only CPT code 77417 (*Therapeutic radiology port image(s)*), we are proposing to assign Procedure Status "B" to align with OPPS payment for this code, which is packaged into payment for the treatment delivery codes, CPT codes 77402, 77407, and 77412 and therefore would not be separately reportable under the PFS. Similarly, it is packaged under the OPPS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments requesting that CMS change the APC assignment for CPT codes 77407 and 77412.

Response: We consider comments regarding APC assignments to be outside the scope of this final rule. We refer commenters to the CY 2026 OPPS final rule for responses to comments regarding APC assignment.

Comment: Many commenters disagreed with the proposed utilization crosswalk for CPT codes 77407 and 77412. Commenters stated that although CMS estimated that CPT codes 77407 and 77412 will represent 50 percent and 45 percent of billed charges respectively, commenters anticipated that CPT code 77407 will be billed at a much higher frequency and CPT code 77412 at a lower frequency. A commenter stated that if use of CPT code 77412 is limited to cases involving breath-hold or gating technology, the commenter anticipated that it would constitute approximately 15 percent of billed charges instead of the proposed 45 percent, and the Medicare program will pay substantially more for radiation treatment than intended.

Response: We appreciate the commenters input on the proposed utilization crosswalk. It is important that the utilization crosswalks be as well-founded as possible in order to value the services appropriately. We We also recognize that in many cases, it is difficult to ascertain how services furnished in the past would be most accurately reported using a future code set. We have reviewed the disparate information and recommendations presented by relevant specialty groups and experts as reflected in public comments and through the AMA RUC recommendations, and are finalizing a modified crosswalk that specifically adjusts downward the estimated portion that 77412 would be reported compared to 77407 based on commenters' who represent those who provide care in the non-facility setting. . Specifically , we are modifying the utilization crosswalk to crosswalk 35 percent of the utilization to CPT code 77412 and 55 percent of the utilization to CPT code 77407.

Comment: Some commenters described congressional action to remove radiation oncology services from the PFS entirely. Other comments requested site-neutral adjustments to ensure equivalent payment across settings.

Response: As commenters are aware, we do not have the statutory authority to remove radiation oncology services from the PFS entirely. The statutory authorities and formulas that govern the PFS and OPPS, especially for annual updates, are unique. At this time, we do not believe that the accuracy of PFS payment is necessarily improved by ensuring equivalent payment across settings . However, we remain open to additional data that could help us as we develop further policies with respect to these services.

Comment: Some commenters recommended displaying only the professional component for CPT code 77387 to avoid billing confusion. A commenter requested that CMS update the Medicare Claims Processing Manual to include language explaining that CPT codes 77387-26 should be reported regardless of the place of service, when performed. Another commenter stated that it is confusing to allow the professional component of CPT code 77387 to be billed with the treatment delivery codes, since the code description states, "including imaging guidance, when performed".

Response: We appreciate the commenters' response to our request for strategies to mitigate billing confusion. We do not believe that a change to billing guidance is needed at this time, especially given the lack of consensus regarding the best approach to this novel circumstance. Because the RVUs assigned to CPT 77387-26 and 77386 billed globally will be the same, any initial confusion as to which of these

codes should be reported will not have an impact on payment. In the alternative, if we were to eliminate use of one or the other of these billing mechanisms in advance, then any entity not conforming to our envisioned approach would be unable to receive payment. Once a consensus approach to reporting these services under this construct emerges, we anticipate updating the guidance. We refer the commenter to the CPT Editorial Panel for additional information regarding the decision to allow billing CPT code 77387 with the treatment delivery codes.

After consideration of comments received, we are finalizing our proposal to utilize the relationship between the proposed OPPS APC relative weights for APCs 5621, 5622, and 5623 to inform the valuation of PE-only CPT codes 77402, 77407, and 77412, with the additional refinement to the utilization crosswalk described earlier in this section.

C. Superficial Radiation Therapy (CPT codes 77X05, 77X07, 77X08, and 77X09)

Superficial radiation therapy is currently provided using CPT code 77401 (*Radiation treatment delivery, superficial and/or ortho voltage, per day*) in conjunction with CPT code 77280 (*Therapeutic radiology simulation-aided field setting; simple*) and HCPCS code G6001 (*Ultrasonic guidance for placement of radiation therapy fields*).

In October 2020, HCPCS code G6001 was identified by the RAW via the CMS/Other Medicare utilization over 20,000 screen. In January 2021, the RUC recommended referring G6001 to CPT to develop new code(s) that reflect the different process of care between the two specialties (dermatology and radiation oncology). After a 2-year delay to allow time for re-review, the CPT Editorial Panel created four codes and a new subsection to report surface radiation therapy in September 2024. These codes will replace CPT code 77401 and HCPCS code G6001 which were scheduled for deletion by the CPT Editorial Panel and recommended for deletion by CMS, respectively. This code family was surveyed for the January 2025 RUC meeting.

The new codes are as follows:

- 77X05: *Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting*
- 77X07: *Surface radiation therapy, superficial, delivery, <150 kV, per fraction (eg, electronic brachytherapy).*

- 77X08: *Surface radiation therapy, orthovoltage, delivery, >150-500 kV, per fraction*
- 77X09: *Surface radiation therapy, superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to the code for primary procedure).*

We proposed the RUC-recommended work RVU for the two codes in the family that have a work RVU. We proposed a work RVU of 0.77 for CPT code 77X05 and a work RVU of 0.30 for CPT code 77X09.

Similar to our approach for the radiation oncology treatment delivery codes discussed above, we believe that using the relationship between the relative weights of the OPPS APCs to which codes in this family are assigned likely more accurately reflect the actual costs of these services compared to use of direct PE input and PE allocation methodologies. Therefore, similar to our proposal for radiation treatment delivery services, we proposed to use this relationship to establish the RVUs for the PE portion of these services.

We proposed to utilize the relationship between the proposed OPPS APC assignments for APCs 5621 and 5732 to inform the valuation of PE-only CPT codes 77X07 ((*Surface radiation therapy, superficial, delivery, <150 kV, per fraction (for example, electronic brachytherapy)*)) and 77X08 (*Surface radiation therapy, orthovoltage, delivery, >150-500 kV, per fraction*), and for the technical component of CPT code 77X05 (*Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting*) when paid under the PFS.

In an effort to align the relationship between the PFS payment for this code family with the relationship of the OPPS information used to develop the RVUs, we proposed to assign Procedure Status "B" to the technical component of CPT code 77X09 to align with OPPS of this code whose costs are packaged into payment for the treatment delivery CPT codes 77X07 and 77X08. We are proposing to display CPT code 77X09 in Addendum B with the professional and technical components, where the technical component is non-payable Procedure Status "B," as well as the global service equal to the payable professional component, but are seeking comment on strategies to mitigate possible billing confusion that could result from this relatively novel circumstance where the technical component of a service is bundled but the professional component is separately reported. Specifically, we sought

comments on whether displaying the global service equal to the professional component is problematic, and if it would be preferable to eliminate the global service and display the professional and technical components only in Addendum B.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal of the RUC-recommended work RVUs for CPT codes 77X05 and 77X09. Commenters stated their appreciation that CMS was proposing to delete the 17 HCPCS G codes (G6001-G6017) and recognize the newly revised CPT codes for payment under the PFS.

Response: We appreciate the support for our proposed policies from the commenters.

Comment: Several commenters disagreed with the proposed work RVUs for CPT codes 77X05 and 77X09 stating that the proposed work valuations did not accurately capture the actual workflow or resource intensity associated with these SRT services. Commenters stated that planning and simulation are not a one-time event and that ultrasound imaging is performed at every fraction to verify depth, confirm margins, monitor treatment response and repopulation, and guide adjustments. Commenters also stated that by limiting both planning and imaging to "per course" and assigning minimal work RVUs with no payable technical component for ultrasound, the proposed structure undervalued the time, clinical judgment, and specialized equipment required for SRT. Commenters recommended CMS revalue these services with direct input from SRT interested parties so that payment policy aligns with real-world clinical practice.

Response: While we appreciate the feedback from the commenters, we continue to believe that our proposed work RVUs for CPT codes 77X05 and 77X09, based on the RUC recommendations, are accurate. The proposed work RVU of 0.77 for CPT code 77X05 was based on a RUC crosswalk to CPT code 95991 (*Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed; requiring skill of a physician or other qualified health care professional*) which shares nearly-identical time values and has an intensity value which would be typical for radiation therapy. CPT code 77X09 was valued based on the 25th percentile from the RUC survey and has a work RVU that falls in the median

range of other add-on services with roughly 10 minutes of intraservice and total time on the PFS. In both cases, we believe that the proposed work RVUs accurately capture the work and intensity of these services.

We also note that while the technical component for ultrasound guidance is not separately payable, it is bundled into the valuation for 77X05 and 77X09. Specifically, we redistributed the PE RVUs that were previously assigned to the G codes describing ultrasound guidance into the valuation for the other codes in the SRT code family.

Comment: Several commenters disagreed with the proposal to utilize the relationship between the payment rates for APCs 5621 and 5732 to inform the valuation of PE-only CPT codes 77X07 and 77X08, and for the technical component of CPT code 77X05. Commenters stated that SRT services are overwhelmingly performed by dermatologists in office-based settings and that the shielding requirements and equipment required to furnish SRT differ significantly from other modalities of radiation therapy and treatment delivery. Commenters stated that capital-intensive resources attributable to other radiation services are not applicable to office-based SRT and therefore the relative weights of the OPPS APCs for for CPT codes 77X05, 77X07, and 77X09 are irrelevant to the PE costs associated with performing these services; commenters stated that the RUC's recommended direct PE inputs more accurately measure typical costs for providing care in the office setting than do nonexistent OPPS data.

Response: We acknowledge these concerns from the commenters, as SRT services are infrequently provided in the hospital setting. However, the PFS claims data indicates that there is a minority of SRT services that do take place in the hospital setting, approximately 2 percent of the overall total.. As we stated in the proposed rule, we believe that using the relationship between the relative weights of the OPPS APCs to which codes in this family are assigned more accurately reflect the actual costs of these services compared to use of the direct PE inputs as recommended by the RUC and CMS' PE allocation methodologies. We reiterate that we calculated the RVUs for these codes so that the overall PE and MP RVUs for these services represent the same share of total PE and MP RVUs in CY 2025 and CY 2026. Therefore, while the RVUs for certain combinations of services may differ between CY 2025 and CY 2026, in aggregate, the total PE and MP RVUs for these services were calculated to be similar.

Comment: Many commenters disagreed with the use of PE associated with ultrasound image guidance being bundled into the CPT code 77X07 through the use of the OPPS crosswalk. Commenters stated that not all SRT machines are equipped with ultrasound capabilities and even when radiation devices include an integrated ultrasound wand, ultrasound is not necessarily performed with each fraction of radiation delivery. Commenters stated that CMS has proposed PE RVUs for CPT code 77X07 that incorporated the cost of ultrasound, resulting in payment regardless of whether ultrasound is actually furnished. Commenters cited two peer-reviewed studies that found no demonstrated clinical benefit of using ultrasound guidance for superficial radiation treatment[68], and stated that ultrasound is not medically necessary for the treatment of superficial skin cancers and is widely considered low-value care. Commenters cited two peer-reviewed studies that found no demonstrated clinical benefit of using ultrasound guidance for superficial radiation treatment[69],[70], and stated that ultrasound is not medically necessary for the treatment of superficial skin cancers and is widely considered low-value care. Commenters also stated that the National Comprehensive Cancer Network (NCCN) Guidelines states that "The use of IGRT for other types of radiotherapy to treat skin cancer is considered unnecessary." Commenters stated that this would provide payment for a service that five of the MACs have proposed to exclude from coverage, citing a lack of medical necessity. Commenters stated that this could lead to inconsistencies between coverage and payment policy as well as increase the potential for billing confusion among physicians. Other commenters cited studies supporting the efficacy of IGSRT[71],[72],[73],[74].

Response: While we appreciate the concern from the commenters, we believe that one of the advantages of bundling in the payment for ultrasound guidance, consistent with the OPPS, would eliminate financial incentives to provide ultrasound guidance where it may be of questionable value. As we stated earlier in this section, services in this code family that describe technical costs and are not

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[68] Gronbeck, C., et al. (2025). Image guidance contributes substantial cost and rarely informs dosimetry management in superficial radiotherapy: A national Medicare analysis. *Journal of the American Academy of Dermatology, 93* (3), 795-797.
[69] Gronbeck, C., et al. (2025). Image guidance contributes substantial cost and rarely informs dosimetry management in superficial radiotherapy: A national Medicare analysis. *Journal of the American Academy of Dermatology, 93* (3), 795-797.
[70] Gronbeck, Christian, et al. (2024) Volume and distribution of radiotherapy performed by dermatologists from 2016 to 2021: A national Medicare trend analysis. *Journal of the American Academy of Dermatology,. 91*(2), 341-344.
[71] Yu, L, et al (2021). The Treatment of Non-Melanoma Skin Cancer with Image-Guided Superficial Radiation Therapy: An Analysis of 2917 Invasive and In Situ Keratinocytic Carcinoma Lesions. Oncology and Therapy, 9(1), 153- 166
[72]Tran, A et al. (2023). Analysis of image-guided superficial radiation therapy (IGSRT) on the treatment of early-stage non-melanoma skin cancer (NMSC) in the outpatient dermatology setting. Journal of Cancer Research and Clinical Oncology, 149(9), 6283-6291.
[73] McClure, E. M., et al. (2023). Image-guided superficial radiation therapy has superior 2-year recurrence probability to Mohs micrographic surgery. Clinical and Translational Radiation Oncology ,43
[74] Yu, L et al. (2022). Local control comparison of early-stage non-melanoma skin Cancer (NMSC) treated by superficial radiotherapy (SRT) and external beam radiotherapy (XRT) with and without dermal image guidance: a meta-analysis. Discover Oncology, 13(1):129

separately payable under the OPPS will not be separately payable under the PFS, because the associated costs are incorporated into the costs for separately paid codes. We will assign the procedure status of "B" to the CPT code describing ultrasound guidance; this will mean that the use of ultrasound guidance will not vary the payment made under the PFS.

Comment: Some commenters disagreed with the coding revision to collapse image-guided superficial radiation therapy (IGSRT), superficial radiation therapy (SRT), and electronic brachytherapy into one "surface radiation" code family, stating that this misrepresents how these services are delivered. The commenters stated that combining these services obscures differences in personnel, workflow, and outcomes, and will lead to undervaluation of IGSRT. Commenters suggested that CMS adopt a series of G-codes describing IGSRT.

Response: We do not agree with commenters that the CPT code set reflects an inappropriate grouping of services, and we do not see a Medicare program need to develop G-codes in order to reflect the variations described by commenters.

Comment: Many commenters disagreed with the coding revisions to CPT code 77X09 which would restrict its billing to a single use per treatment course. Commenters stated that under these billing restrictions, patients face a higher risk of recurrence from underdosing (leading to recurrence) or avoidable toxicity from overdosing. Commenters stated that the proposed coding change would particularly harm rural and underserved patients and force many dermatology practices to discontinue offering SRT services.

Response: The coding revisions to CPT code 77X09 described by the commenters were adopted by the CPT Editorial Panel as part of its revision of superficial radiation services. We direct concerns over the "per course of treatment" aspect of CPT code 77X09's code descriptor to the CPT Editorial Panel for additional explanation. We believe that on balance, the new coding set represents an improvement from the current coding, much as we believe that the use of OPPS cost data for these services will be more accurate than other valuation methodologies, and that the alternative to using CPT's coding would be to maintain the current set of G-codes. We remind the commenters that CMS does not have the authority to change the code descriptors for CPT codes, and we believe that the SRT codes were designed to function

together as a group which would not warrant creating a separate G code with a modified code descriptor to replace CPT code 77X09.

For the comments that this coding revision would harm rural and underserved patients, we do not agree. Since ultrasound guidance is bundled into the valuation for CPT code 77X09, the valuation reflects the resource costs associated with furnishing the ultrasound guidance.

Comment: Commenters expressed concern about a gap in the new coding structure and coding instructions. Specifically, commenters stated that the new coding will create barriers to well-established use of orthovoltage radiation treatment for non-malignant musculoskeletal disorders.

Response: We remind commenters that, in cases where a service is not described by an existing CPT code, unlisted codes may be reported.

Comment: Some commenters stated that CMS failed to provide a transparent and comprehensive analysis supporting its proposed PE RVUs for SRT services. The commenters stated that CMS should publish the PE RVUs that would result under the standard PE methodology alongside the OPPS-derived PE RVUs.

Response: We note that an alternative to our proposal to value the new CPT codes would be to establish G-codes to maintain the pre-existing coding and valuation. We have previously taken this approach with regard to certain radiation therapy services.

TABLE A-E9: SUMMARY OF CODING FOR RADIATION ONCOLOGY TREATMENT DELIVERY AND SUPERFICIAL RADIATION THERAPY CODES

CPT Code-Modifier	Long Descriptor	OPPS Payment Status	OPPS Proposed APC	PFS Procedure Code Status	PE Only Code?
77402	Radiation treatment delivery; Level 1 (for example, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed	S	5621	A	✓
77407	Radiation treatment delivery; Level 2, single isocenter (for example, 3D or IMRT), photons, including imaging guidance, when performed	S	5622	A	✓
77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (for example, 2D, 3D, or IMRT) OR a single isocenter photon therapy (eg, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed	S	5623	A	✓
77417	Therapeutic radiology port image(s)	N	N/A	B	

CPT Code-Modifier	Long Descriptor	OPPS Payment Status	OPPS Proposed APC	PFS Procedure Code Status	PE Only Code?
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed	N	N/A	A	
77387-26 Professional component				A	
77387-TC Technical component				B	
77X05	Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting	S?	5732	A	
77X05-26 Professional component				A	
77X05-TC Technical component				A	
77X07	Surface radiation therapy, superficial, delivery, <150 kV, per fraction (for example, electronic brachytherapy)	S?	5621	A	✓
77X08	Surface radiation therapy, orthovoltage, delivery, >150-500 kV, per fraction	S?	5621	A	✓
77X09	Surface radiation therapy, superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to the code for primary procedure)	N	N/A	A	
77X09-26 Professional component				A	
77X09-TC Technical component				B	

D. Proton Beam Treatment Delivery (CPT codes 77520, 77522, 77523, and 77525)

PFS payment amounts for proton beam treatment delivery services are currently determined by local Medicare Administrative Contractors (MACs). As discussed in CY 2021 rulemaking (85 FR 84625 through 84626), we have not previously established RVUs for these services due to the unique nature of the equipment costs associated with these services compared to other capital costs addressed by our usual PE methodology. Given the proposals described above to establish RVUs for the new and revised CPT codes for Radiation Oncology and Superficial Radiation Treatment Delivery Services, we sought comments on whether we should adopt a similar approach to establish RVUs for proton beam treatment delivery services. We note that these services are assigned to APCs 5623 and 5625 under the OPPS with established Medicare payment rates (unlike the contractor pricing in place for these services under the PFS). We specifically seek comments on how we may establish national pricing and total RVUs for these services to maintain relativity within the PFS. For example, would using the overall ratio between OPPS and PFS payment for radiation oncology treatment services to establish initial year RVUs for proton beam

treatment delivery services accurately reflect the relative resources involved in furnishing the services? Alternatively, would it be more appropriate to consider the overall difference between the OPPS and Medicare payment as currently determined by the MACs for these services, or are there other alternative methods we should consider? We welcome comments on this topic.

Comment: We received many thoughtful comments in response to this comment solicitation.

Response: We appreciate the commenters for their feedback and will consider it as part of future rulemaking.

(26) Combination COVID-19 Vaccine Administration (CPT codes 90480 and 90481)

In September 2024, the CPT Editorial Panel created a new add-on code, 90481 (*each additional component administered (List separately in addition to code for primary procedure*)), to report when each additional non-COVID vaccine component is administered with the COVID-19 vaccine. CPT code 90480 (*Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SAR CoV2)(coronavirus disease [COVID19]) vaccine; first or only component of each vaccine administered*) was revised as part of this family of services.

We received RUC recommendations for CPT code 90480 that affirmed the September 2023 work and PE RUC recommendations. We previously established CPT code 90480 with a procedure status of "X" on the PFS, and the code is therefore not payable under the PFS. Payment for this CPT code is also addressed under previously finalized policies associated with the emergency use authorization declaration. We refer readers back to the CY 2025 PFS final rule (89 FR 97710) for more information on this previously finalized policy.

We also received RUC recommendations for add-on CPT code 90481. The RUC recommendations for this CPT code do not include work or PE inputs as the recommendations suggest that the work and PE is already included in the administration base code and this add-on code is intended for tracking purposes of the second vaccine.

We proposed to maintain procedure status "X" for CPT code 90480 and assign procedure status "X" to CPT code 90481.

We received public comments on combination COVID vaccine administration services. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to maintain procedure status "X" for CPT code 90480 and assign procedure status "X" to new CPT code 90481.

Response: We appreciate the commenters for their support.

Comment: Some commenters stated that they have concerns with combination COVID vaccines being procedure status "X" on the PFS as they believe it could create confusion with payment should combination COVID vaccines become available to the market in the future and there are no administration codes. Commenters were also concerned with inadequate payment for the counseling portion of vaccine administration and requested that CMS create a G code for vaccine administration of combination COVID vaccines.

Response: We acknowledge commenters' concerns and appreciate feedback regarding broader COVID vaccine payment policy. We did not propose any policy changes for preventative vaccine administration for the CY 2026 PFS final rule, and we therefore consider those topics out of scope for the purposes of this discussion. We also acknowledge commenters' request for a HCPCs G code for combination covid vaccine administration. We remind commenters that CPT code 90481 is meant to be a tracking code only, so we do not believe the creation of a HCPCs G code for administration would be appropriate at this time.

Comment: Several commenters requested that CMS publish the RUC-recommended work RVU of 0.25 and PE and MP RVUs for CPT code 90480 in Addendum B on a display basis so other payors could utilize these relative values.

Response: We agree with commenters' request to display RVUs for CPT code 90480 and will update Addendum B to reflect the RVUs for this service for display purposes only. We will publish the RVUs for its add-on CPT code 90481 as well, should any exist, also for display purposes only.

After consideration of the public comments, we are finalizing as proposed.

(27) Immunization Counseling (CPT codes 90482, 90483, and 90484)

In May 2024, the CPT Editorial Panel created three new time-based CPT codes 90482, 90483, and 90484 to report vaccine counseling performed where a vaccine is not administered. CPT code 90482 (*Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; 3 minutes up to 10 minutes*), CPT code

90483 (*Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 10 minutes up to 20 minutes)* and CPT code 90484 (*Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 20 minutes)*. These services were surveyed and reviewed at the September 2024 RUC meeting.

In 2022, CMS created six new HCPCS codes so that Medicaid providers could bill for stand-alone vaccine counseling, "State Health Official Letter #22-002 "Medicaid and CHIP Coverage of Standalone Vaccine Counseling"[75]. The six HCPCS codes are:

G0310 (*Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 5 to 15 mins time. (This code is used for Medicaid billing purposes.))*

G0311 (*Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 16-30 mins time. (This code is used for Medicaid billing purposes.))*

G0312 (*Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 5 to 15 mins time. (This code is used for Medicaid billing purposes.))*

G0313 *Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 16-30 mins time. (This code is used for Medicaid billing purposes.)*

G0314 *Immunization counseling by a physician or other qualified health care professional for COVID-19, ages under 21, 16-30 mins time. (This code is used for the Medicaid Early and Periodic Screening, Diagnostic, and Treatment Benefit (EPSDT.)*

G0315 *Immunization counseling by a physician or other qualified health care professional for COVID-19, ages under 21, 5-15 mins time. (This code is used for the Medicaid Early and Periodic Screening, Diagnostic, and Treatment Benefit (EPSDT.)*

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[75] https://www.medicaid.gov/state-resource-center/downloads/stnd-vacc-cou-spec-hcpcs-codes.pdf.

The RUC requested that CMS delete HCPCS codes G0310-G0313, and replace them with the new CPT codes 90482, 90483, and 90484. However, we proposed to assign status indicator ("I") to each of these three services, as not valid for Medicare purposes. Medicare uses other coding for reporting of, and payment for immunization counseling. We are not proposing any work RVUs or PE RVUs for any of the three new CPT codes.

Comment: We received many comments requesting that CMS make CPT codes 90482, 90483, and 90484 payable under the PFS, or at least provide details on what other CPT codes are available to report these services.

Response: As we stated in the proposed rule, (90 FR 32593 through 32597) Medicare uses other coding for reporting of and payment for immunization counseling. Under the PFS practitioners may report and receive payment for immunization counseling where an immunization is not administered under evaluation and management visits (E/M) coding. Practitioners may select the level of E/M visit based on the visit's level of medical decision making or report these visits based on time as appropriate.

Comment: Several commenters requested that CMS publish the RUC-recommended work RVUs and PE and MP RVUs for CPT codes 90482, 90483, and 90484 in Addendum B on a display basis so other payors could utilize these relative values.

Response: We agree with commenters' request to display RVUs for CPT codes 90482, 90483, and 90484 and will update Addendum B to reflect the RVUs for this service for display purposes only. After reviewing all the other public comments we are finalizing as proposed.

(28) Colon Motility Services (CPT codes 91124 and 91125)

In April 2023, the Relativity Assessment Workgroup (RAW) identified CPT codes 91120 and 91122 as reported together 75 percent of the time or more based on 2021 Medicare claims data. The RUC noted that these services are reported together 95 percent of the time and recommended that the specialty societies work with the CPT Editorial Panel to develop a code bundling solution. In May 2024, the CPT Editorial Panel created two new codes, CPT code 91124 (*Rectal sensation, tone, and compliance study (for example, barostat))* and CPT code 91125 (*Anorectal manometry, with rectal sensation and rectal balloon expulsion test, when performed)* to describe these services to replace CPT codes 91120 and 91122. The two new codes were surveyed for the September 2024 RUC meeting.

For CY 2026, the RUC-recommended a work RVU of 3.05 for CPT code 91124 and 2.70 for CPT code 91125. We are proposing these RUC recommendations without refinement.

For the direct PE inputs, we disagreed with the RUC-recommended 17 minutes of clinical labor associated with CA013 (Prepare room, equipment and supplies) for CPT code 91125. We proposed a time of 2 minutes for CA013, which is the standard time for this PE input. We proposed the RUC recommendation of 17 minutes of clinical labor time for CA013 for CPT code 91124 to account for a previous input of 15 minutes to calibrate equipment in similar codes. We recognize it is not typical to have different values for the same clinical labor activity across a code family, and we welcome comments as to the appropriateness of these refinements.

We disagreed with the RUC-recommended 30 minutes of clinical labor associated with CA024 (Clean room/equipment by clinical staff) for CPT 91124 as we stated that we believed this is unnecessarily long and does not match similar services. We proposed a CA024 time of 10 minutes for both codes (CPT 91124 and 91125) based off reference CPT code 45300 (*Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)*).

We also proposed to refine the SM015 supply (Enzymatic detergent) to a quantity of 4 ounces for both codes, to match similar inputs for similar services. We sought comment on the appropriateness of this refinement, as we do not believe that 120 ounces of the SM015 supply would be typical or necessary given that no HCPCS code on the entire PFS uses more than 8 ounces of this supply.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters were generally supportive of our proposal of the RUC-recommended work RVU of 3.05 for CPT code 91124 and 2.70 for CPT code 91125.

Response: We appreciate the commenters for their support, and we are finalizing our proposed work RVUs for CPT code 91124 and 91125.

Comment: Several commenters disagreed with the PE refinement from 17 minutes to 2 minutes for the CA013 clinical labor time for CPT code 91125. The commenters noted that CMS may have missed the supporting materials in the PE summary of recommendations (SOR). Commenters noted that 17 minutes of clinical labor time is recommended for both codes to prepare and calibrate the equipment

and to test the catheter to ensure there is no leakage; commenters stated that this was true for both CPT codes 91124 and 91125. For CPT code 91124, commenters listed out four specific activities associated with this clinical labor time, and for CPT code 91125, commenters listed out the nine specific activities required to adequately prepare the room, equipment, and supplies.

Response: We appreciate the commenters for providing clarification and delineating the steps that are necessary to prepare the room, equipment, and supplies. After consideration of public comments, and a re-review of the PE SOR, we were persuaded by commenters that 17 minutes would be appropriate for this direct PE input. We are therefore finalizing 17 minutes of CA013 clinical labor time for CPT code 91125.

Comment: For the CA024 clinical labor time (clean room/ equipment by clinical staff), commenters disagreed with the proposed direct PE refinements for CPT codes 91124 and 91125. Commenters clarified that the catheter used in both procedures is flexible, not rigid and that flexible scopes typically require more time for cleaning than rigid scopes. A commenter suggested CMS to finalize the direct PE inputs for CPT codes 91124 and 91125 as recommended by the RUC. A commenter disagreed specifically with the reduction of clinical labor time associated with cleaning the room, equipment and supplies, as well as the proposed amount of cleaner. The commenter suggested finalizing 30 minutes of cleaning time for consistency with cleaning standards for flexible scopes. The commenter also suggested a crosswalk to the direct PE inputs for CPT code 45378 (*Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*). Additionally, the commenter pointed out an inconsistency in CMS' recommendations for room and equipment preparation time for CPT codes 91124 and 91125, requesting CMS review supporting materials.

Response: We appreciate the clarification provided by commenters regarding the cleaning time associated with these procedures. However, we continue to believe that 30 minutes of CA024 clinical labor time would not be typical for these procedures. The standard cleaning time for a rigid scope is 10 minutes and the standard time for a flexible scope is 30 minutes; however, CPT codes 91124 and 91125 include catheters, not scopes. While these two codes do contain an SD216 balloon catheter among their direct PE inputs, we do not typically assign 30 minutes of CA024 cleaning time for cleaning the catheter;

instead, our standard time for catheter cleaning is 3 minutes. We agree that CPT codes 91124 and 91125 require more time than the standard value for the cleaning tasks associated with the CA024 clinical labor activity, which is why we proposed 10 minutes for this task. When evaluating the crosswalk code (CPT code 45378) suggested by commenters, we also noted that this code had only 3 minutes of CA024 cleaning time, which did not support the requested increase in cleaning time. Therefore, we continue to believe that our proposed 10 minutes of CA024 clinical labor time is accurate for these two codes, and we are finalizing as proposed. We did not see sufficient rationale provided to support a change in valuation at this time, however, we welcome additional information regarding this supply.

Comment: A few commenters also requested CMS to restore the (enzymatic detergent) supply to 120 ounces, based on the vendor's cleaning instructions.

Response: We disagree with commenters that 120 ounces would be appropriate based on the vendor instructions. Among the approximately 70 other codes on the PFS that use the SM015 supply, the typical quantity in use is 4 ounces and no codes use more than 8 ounces. We do not agree that 120 ounces of this product would be typically required for routine cleaning activities. However, we will increase the SM015 supply input for this code from 4 to 8 ounces to match the highest supply quantity amongst codes currently paid under the PFS (CPT codes 30300 and 30560) to reflect the concerns of the commenters.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 91124 and 91125 as proposed, with the modification to the CA017 clinical labor time for CPT code 91125 and the modification to the SM015 supply quantity, as previously detailed.

(29) Dark Adaptation Diagnostic and Screening Services (CPT codes 92284 and 92288)

In 2023, specialty societies prepared and submitted a Category I Code Change Application to the CPT Editorial Panel to create CPT code 92288 *(Screening dark adaptation measurement (for example, rod recovery intercept time), with interpretation and report)*, which describes the screening test for retinal and optic nerve disease. This code was created to differentiate between diagnostic dark adaptation testing and screening testing that has possibly been reported under CPT code 92284 *(Diagnostic dark adaptation examination (for example, rod and cone sensitivities, rod-cone breakpoint), with interpretation and report)*. The CPT Editorial Panel also added a parenthetical to CPT code 92284, to describe how the diagnostic dark adaptation test is conducted to identify patients with macular degeneration or inherited

retinal diseases when they have symptomatic visual loss without any identifiable cause or clinical examination.

CPT code 92288 describes a screening service that has not been determined to be a preventive service under Section 1861 of the Social Security Act and as such is not covered under Medicare. We are proposing to assign status indicator ("N") to this service, as a non-covered service. We will list the RUC-recommended RVUs for display purposes only.

In the CY 2023 PFS final rule we finalized a work RVU of 0.00 for CPT code 92284 as proposed (87 FR 69513). The RUC had surveyed this procedure in 2021, reviewed the survey results for the procedure and recommended 1 minute of pre-service time, 3 minutes of intraservice time, 1 minute of immediate post-service time, totaling 5 minutes, all of which reduced the surveyed times. The RUC also recommended a work RVU of 0.14. We disagreed with the RUC-recommended work RVU of 0.14 for CPT code 92284. We found that the recommended work RVU did not adequately reflect reductions in physician time, since the diagnostic screening is usually completed during an E/M visit and largely consists of interpreting machine generated results.

For this latest review of CPT code 92284 for CY 2026, we disagree with the RUC-recommended work RVU of 0.32 and proposed a work RVU of 0.29 for CPT code 92284 based on a crosswalk to code CPT 92132 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), anterior segment, with interpretation and report, unilateral or bilateral),* for which we finalized 0.29 work RVU in the CY 2025 PFS. Our proposed work RVU was also supported by reference to CPT code 71110 (*Radiologic examination, ribs, bilateral; 3 views*), with a work RVU of 0.29. Both codes have intraservice work times of 6 minutes and total times of 8 minutes. While the intraservice work time of both reference codes is 1 minute less than the RUC-recommended median survey time for CPT code 92284, they each have 1 minute for pre-service and post- service times. We believe it is more appropriate to use these reference codes than the RUC-recommended cross walk to CPT 92282 *(Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral)* with a work value of 0.32 RVU because we believe the RUC-recommended intraservice work time and work RVU are overstated relative to the current intraservice work time and work RVU for CPT code 92284. Additionally, we also searched for

crosswalks to CPT codes with the same intraservice time and a range of similar pre-and post-service times and found that the recommended work RVU of 0.32 fell near the top of this range, which would not maintain relativity of the work values among the identified CPT codes.

We proposed the RUC-recommended direct PE inputs for CPT code 92284 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters opposed the CMS proposed work RVU of 0.29 for CPT code 92284. These comments recommended that CMS revisit the proposal and finalize the RUC-recommended work RVU of 0.32 for CPT code 92284. Commenters maintained that the CMS proposed work RVU of 0.29 does not accurately account for the necessary time and overall measured intensity/complexity arising from increased medical decision-making related to the advanced analysis to interpret the test results. Several commenters requested that CMS publish the RUC-recommended work RVUs and PE and MP RVUs for CPT code 92288 in Addendum B on a display basis so other payors could utilize these relative values.

Response: We appreciate the commenters for their comments. We continue to believe it is more appropriate to use our proposed work RVU of 0.29 for CPT code 92284 than the RUC-recommended crosswalk to CPT 92282 with a work value of 0.32 RVU. As we stated in the proposed rule, when we searched for other CPT codes with similar time values to CPT code 92284, the RUC's recommended work RVU fell near the top of this range which would not maintain relativity of the work values among the identified CPT codes. We do not believe that the diagnostic dark adaptation examination service being performed in CPT code 92284 would typically have high enough intensity to warrant the RUC's recommended work RVU.

After consideration of these comments, we are finalizing the work RVU and direct PE inputs for CPT code 92284 as proposed, along with finalizing the proposed non-covered status indicator for CPT code 92288. We agree with commenters' request to display RVUs for CPT code 92288; however, we note that the proposed rule already displayed RVUs for this service in Addendum B. We will continue to display these RVUs for the final rule and in future rulemaking.

(30) Coronary Therapeutic Services and Procedures (CPT codes 92920, 92924, 92928, 92933, 92937, 92941, 92943, 92973, 92930, 92945, 93571, and 93572)

In the CY 2013 PFS final rule (77 FR 69063 through 69064), we reviewed 13 new codes to describe percutaneous coronary intervention (PCI) services and assigned bundled status to all the add-on codes for the additional branches off the major coronary arteries because we believed that separately paying for branch-level stents may encourage increased placement of stents. To bundle the work of each new add-on code into its respective base code, we used the RUC-recommended utilization crosswalk to determine what percentage of the base code utilization would be billed with the add-on code, and added that percentage of the RUC-recommended work RVU and physician time for the add-on code to the RUC-recommended work RVU and physician time of the base code.

In September 2022, the CPT Editorial Panel created one new Category I CPT code for percutaneous coronary lithotripsy. The new add-on CPT code 92972 (*Percutaneous transluminal coronary lithotripsy*) was reviewed by the RUC on an interim basis for CY 2024 while the entire PCI code family was referred to the CPT Editorial Panel for restructuring. Subsequently, the code family was revised at the February 2024 CPT Editorial Panel meeting, including the deletion of the bundled add-on codes, and surveyed for the April 2024 RUC meeting.

The following is a list of the CPT codes and their long descriptors: CPT codes 92920 (*Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)*), 92924 (*Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)*), 92928 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); one lesion involving one or more coronary segments*), 92933 (*Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)*), 92937 (*Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed, single vessel major coronary artery and/its branches*), 92941 (*Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, any combination of intracoronary*

stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single major coronary artery and/or its branches or single bypass graft and/or its subtended branches), 92943 (*Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach*), 92973 (*Percutaneous transluminal coronary thrombectomy aspiration mechanical (List separately in addition to code for primary procedure)*), 92930 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); two or more distinct coronary lesions with two or more coronary stents deployed in two or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch*), 92945 (*Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches*), 93571 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; initial vessel (List separately in addition to code for primary procedure)*), and 93572 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; each additional vessel (List separately in addition to code for primary procedure)*).We proposed the RUC-recommended work RVU for all twelve codes in the family. We proposed a work RVU of 8.35 for CPT code 92920, a work RVU of 10.13 for CPT code 92924, a work RVU of 10.00 for CPT code 92928, a work RVU of 11.94 for CPT code 92933, a work RVU of 11.30 for CPT code 92937, a work RVU of 12.72 for CPT code 92941, a work RVU of 13.69 for CPT code 92943, a work RVU of 1.75 for CPT code 92973, a work RVU of 12.00 for CPT code 92930, a work RVU of 15.00 for CPT code 92945, a work RVU of 1.80 for CPT code 93571, and a work RVU of 1.44 for CPT code 93572.

However, we note these work RVUs as recommended by the RUC set new upper ranges for multiple codes in the RUC Database. For example, the proposed work RVU of 12.00 for CPT code 92930

sets a new upper range on RUC Database searches for 000-day global codes with an intraservice time of 75 minutes, with a previous maximum value of 10.25 work RVUs for CPT code 49614 (*Repair of anterior abdominal hernia(s) (that is, epigastric, incisional, ventral, umbilical, spigelian), any approach (that is, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated*), with the same intraservice time and 165 minutes of total time. Similarly, we shared in the RUC's difficulties finding major surgical procedures with the 000-day global period with similar times to use as potential reference or bracket codes.

The RUC did not recommend, and we did not propose any direct PE inputs for these facility-based services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they appreciated and supported the CMS proposal of the RUC-recommended work RVUs for all 12 codes in the family. A commenter also requested CMS exclude these codes from the proposed efficiency adjustment as these codes were just revalued and contained several new codes.

Response: We appreciate the support for our proposed valuations from the commenters; our discussion of the efficiency adjustment can be found in section II.E.2.b of this final rule.

After consideration of the comments, we are finalizing the work RVUs for all 12 codes in the Coronary Therapeutic Services and Procedures family as proposed. We did not propose, and we are not finalizing any direct PE inputs for these codes.

(31) RSV Monoclonal Antibody Administration (CPT codes 96380 and 96381)

In September 2023, CPT created two Category I codes, 96380 (*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional*) and 96381 ((*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection*) to report administration of respiratory syncytial virus (RSV), monoclonal antibody and seasonal dose, with and without counseling. These codes were effective October 6, 2023 for immediate use. At the time, the RUC did an immediate

review of these codes and issued interim recommendations to CMS. The RUC reviewed these codes again at the April 2024 RUC meeting.

We proposed the RUC-recommended work RVU of 0.28 for CPT code 96380 and 0.17 for CPT code 96381. We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed RUC-recommended work and PE inputs for RSV monoclonal antibody administration services. Commenters recommended that CMS engage in ongoing monitoring of payment adequacy as more data is gathered on this service over time. Commenters requested that CMS publish the RUC-recommended work RVUs and PE and MP RVUs for CPT code 96380 and CPT code 96381 in Addendum B on a display basis so other payors could utilize these relative values.

Response: We appreciate the commenters for their support. We agree with commenters' request to display RVUs for CPT code 96380 and 96381; however, we note that the proposed rule already displayed RVUs for these services in Addendum B as both codes have an active status code. We will continue to display these RVUs for the final rule and in future rulemaking.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 96380 and 96381 as proposed.

(32) Remote Monitoring (CPT codes 98975, 98976, 98977, 98978, 98980, 98981, 98984, 98985, 98986, 98979, 99091, 99453, 99454, 99457, 99458, 99473, 99474, 99445, and 99470)

In September 2024, the Current Procedural Terminology (CPT) Editorial Panel added one code and made code revisions to report remote physiologic monitoring (RPM) device supply for 2 to 15 days and 16-30 days within a 30-day period to report RPM parameters; created one new code and code revisions to report RPM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; added three remote therapeutic monitoring (RTM) device supply codes to report respiratory, musculoskeletal and cognitive behavioral therapy for 2 to 15 days and 16 to 30 days within a 30-day period; created one new code and made code revisions to report RTM treatment

management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; and revised remote monitoring guidelines.

Remote physiologic monitoring (RPM) represents the remote monitoring of parameters such as weight, blood pressure, and pulse oximetry to monitor a patient's condition and inform their management. The remote physiologic monitoring code set currently includes CPT codes 99453, 99454, 99091, 99457, 99458, 99473, and 99474 (code descriptors can be found in Table A-E10). For CY 2026, the CPT Editorial Panel created two new RPM codes to describe RPM services that describe less than 16 days of data transmission per 30-day period and less than 20 minutes of interactive communication per month: CPT codes 99445 and 99470. The CPT Editorial Panel also made edits to specify the minimum days of data transmission per 30-day period for CPT code 99454 (new code descriptors and revised code descriptors can be found in Table A-E11). None of the RPM codes (CPT codes 99091, 99474, 99470, 99457, and 99458) met the minimum survey requirements established by the RUC for the January 2025 RUC meeting. As a result, the RUC-recommended that CPT codes 99091, 99474, 99470, 99457, and 99458 be resurveyed after 1 year of utilization data is available for this CPT 2026 code structure. All RPM codes are expected to be reviewed at the January 2028 RUC meeting.

Remote therapeutic monitoring (RTM) represents the monitoring of adherence to at-home therapeutic interventions. RTM can be provided for a variety of conditions, and there are distinct device supply codes that have been created for three types of therapeutic monitoring: respiratory system, cognitive behavioral therapy, and musculoskeletal system monitoring. The remote therapeutic monitoring code set currently includes CPT codes 98975, 98976, 98977, 98978, 98980, and 98981 (code descriptors can be found in Table A-E10). For CY 2026, the CPT Editorial Panel created four new RTM codes to describe RTM services that describe less than 16 days of data transmission per 30-day period and less than 20 minutes of interactive communication per month: CPT codes 98984, 98985, and 98979. The CPT Editorial Panel also made edits to specify the minimum days of data transmission per 30-day period for CPT codes 98976, 98977, and 98978 (new code descriptors and revised code descriptors can be found in Table A-E11). All of the codes in the RTM family are considered new technology (CPT codes 98975, 98984, 98976, 98985, 98977, 98979, 98979, 98980, and 98981) and will be placed on the New Technology list to be reviewed after 3 years of data are available (April 2030).

TABLE A-E 10: CY 2025 REMOTE MONITORING CODES

Code	Long Descriptor
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, each 30 days
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, each 30 days
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, each 30 days
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)

TABLE A-E11: PROPOSED CY 2026 REMOTE MONITORING CODES

Code	Long Descriptor
99453	No changes for CY 2026
99445	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial: device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period
99091	No changes for CY 2026
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes

Code	Long Descriptor
99457	No changes for CY 2026
99473	No changes for CY 2026
99474	No changes for CY 2026
99458	No changes for CY 2026
98975	No changes for CY 2026
98984	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period
98985	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period
98986	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period
98979	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes
98980	No changes for CY 2026
98981	No changes for CY 2026

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters overwhelmingly supported the creation and adoption of CPT codes describing 2 to15 days of monitoring and the first 10 minutes of treatment management services. Commenters stated that these services could be valuable for beneficiaries with acute conditions or are more stable in their treatment. Some commenters did not support the creation of these codes, as they believe that more days of monitoring could deliver greater clinical value and that these codes may increase the potential for inappropriate billing practices.

Response: We appreciate the commenters for their support in our proposal to adopt the new CPT codes. While we understand the concerns presented by commenters who were apprehensive about the adoption of these new codes, we would like to emphasize that services paid under the Physician Fee Schedule, including the new remote monitoring codes, must be reasonable and necessary for the diagnosis and treatment of illness or injury. We continue to believe that the new remote monitoring CPT codes may be reasonable and necessary for some beneficiaries who require remote monitoring services.

Comment: Many commenters did not support any of our proposals for valuation that were lower than the RUC recommendations, and many commenters believe that RTM and RPM are generally undervalued.

Response: We appreciate the commenters for this information. We will consider additional refinements in future rulemaking.

Comment: Several commenters requested clarification around the coding structure of the new CPT codes, specifically around the base and add-on code structure.

Response: We would like to offer further clarification on the coding structure of the new remote monitoring codes. The 2 to 15 day codes (99445, 98984, 98985, and 98986) and 16 to 30 day codes (99454, 98976, 98977, 98978) are not additive and are not a base and add-on code structure. Billing practitioners would only bill for one of those codes for the appropriate number of days of data transmission per 30 days. In addition, the treatment management services describing the first 10 minutes (99470 and 98979) and first 20 minutes (99457 and 98980) of service are also not additive. Billing practitioners would choose the most appropriate code for the time spent that calendar month. In instances where more than 20 minutes of treatment management is needed after either 99457 or 98980 is billed, 99458 or 98981 can be used. Please refer to the CPT codebook for additional information on the structure of these CPT codes.

Comment: Commenters noted that they found Table A-E11 in the proposed rule unclear.

Response: We would like to clarify to commenters that Table A-E11 was intended to display the long descriptors for the Remote Therapeutic and Remote Physiologic Monitoring code families. It was not meant to encompass all edits that were made to the CPT codebook language. We will be adopting all descriptors, guidelines, prefatory language, and parenthetical changes made to the Remote Monitoring section of the 2026 edition of the CPT codebook. Please refer to the CPT codebook for additional information.

Comment: Several commenters requested a variety of changes to the requirements for RPM and RTM, including allowing both new and established patients to receive RPM services, allowing RPM and RTM to be billed concurrently, allowing payment for multiple devices, and allowing billing during the global period. Commenters requested that additional data collection be required for billing (including

greater specificity about the types of data that can be collected), implementing duration limits, and adding additional technology and EHR requirements. Commenters also requested changes to the coding for RPM and RTM, including revising code descriptors to align all codes to account for calendar months as opposed to 30-days, creating condition-agnostic RTM coding, creating additional RTM coding for other conditions, and creating coding specific to Software as a Service (SaaS) or AI-generated analysis instead of just provider analysis.

Response: We appreciate the commenters for this information and will consider for future rulemaking. We would also like to refer interested parties to the CY 2024 PFS final rule (88 FR 78882 through 78883), where some of this information was clarified.

Comment: Several commenters requested that we allow additional billing practitioners and clinical staff to furnish remote monitoring services, such as pharmacists, registered dieticians, and athletic trainers.

Response: We appreciate the commenters for their input. As these practitioners do not have the appropriate benefit category to furnish these services, we lack the statutory authority to expand the benefit categories for billing practitioners.

Comment: Several commenters requested that we eliminate geographic adjustments or develop a national price floor for remote monitoring services, as technology costs are fixed and do not vary geographically like labor or practice expense.

Response: Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs and are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment,

supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

Comment: Several commenters requested that we update practice expense inputs for remote physiologic and remote therapeutic monitoring to account for software such as a medical device, hardware, and additional technology inputs as direct PE. Commenters recommended CMS make revisions to PE inputs to account for both the device and the supporting infrastructure, software (including Software as a Service (SaaS), or other technology inputs.

Response: We appreciate the commenters for this information and we will consider input and recommendations to update practice expense inputs for future rulemaking. Please see section I(1)(b) of this rule for additional discussion of software as a service.

Comment: Several commenters requested clarification on whether time spent providing audio-only communication with the patient/caregiver (for example, telephone calls) could count towards the time counted for the interactive communication portion of CPT codes 98979, 98980, 98981, 99470, 99457, and 99458. Commenters also requested that we clarify that technological communications, such as secure messaging, asynchronous chat, automated bi-directional messaging, and AI prompts, count towards time for the interactive communication portion of CPT codes 98979, 98980, 98981, 99470, 99457, and 99458. Commenters requested that documented in-clinic discussions meet the interactive communication requirement.

Response: We are clarifying that we are adopting the CPT language around this requirement. The CPT code book states that CPT Codes 98979, 98980, 98981, 99470, 99457, and 99458 "require a live, interactive communication with the patient/caregiver. The interactive communication contributes to the total time, but it does not need to represent the entire cumulative reported time of the treatment management service." We are not specifying further exclusions for the types of communications that can be had with the patient/caregiver, so long as they meet the CPT specifications. For in-clinic discussions, no time or effort should be counted more than once toward the required time for any services.

Comment: A few commenters requested clarification regarding new RTM CPT codes and the "sometimes therapy" designation.

Response: We note that the new RTM codes 98979, 98984 and 98985 will be designated as ''sometimes therapy'' codes since they are based on RTM codes we designated as sometimes therapy in the CY 2022 PFS final rule. The "sometimes" therapy designation means that the services can be billed outside a therapy plan of care (POC) by a physician and certain NPPs, when appropriate; and always require a POC therapy modifier when furnished by a physical therapist (PT) or occupational therapist (OT), or by a therapy assistant under the PT's or OT's supervision, or speech-language pathologist. When furnished by a physical therapist assistant (PTA) or occupational therapy assistant (OTA), RTM codes generally also require the CQ or CO modifier, respectively, in addition to the POC therapy modifier (GP or GO) when the threshold established via the de minimis or 10 percent standard is met or exceeded for the statutorily required payment adjustment that applies to therapy services provided in whole or in part by PTAs and OTAs. The de minimis standard policy including how to determine when the CQ/CO modifiers are applied including an RTM billing example is found on the Therapy Services website in a document titled: Billing Examples Using CQ/CO Modifiers for Services Furnished In Whole or In Part by PTAs and OTAs at: https://www.cms.gov/medicare/coding-billing/therapy-services/billing-examples-using-cq/co-modifiers-services-furnished-whole-or-part-ptas-and-otas.

For the RTM codes designated as sometimes therapy, we are clarifying our policy about the appropriate use of the CQ/CO modifiers for services of PTAs and OTAs apply to the new RTM code 98979. However, the CQ/CO are not applicable to the RTM device codes 98984 and 98985 as they are based on the exiting codes 98976 and 98977. We previously clarified this CQ/CO modifier RTM device code policy for codes 98976 and 98977 in the CY 2022 PFS final rule (86 FR 65116 and 65176) and provided an educational article (MM12446) with the release of Transmittal R11118CP (Change Request 12446) in addition to the above document link on the Therapy Services webpage. The related policy for the new and revised RTM codes will also be available after the CY 2026 PFS final rule is issued via a Transmittal for the CY 2026 Annual Update of Therapy Codes.

Comment: A commenter requested that CMS default to State law as it relates to who can assist therapists in the provision of RTM services.

Response: While we appreciate the commenters' concern regarding the shortage of therapy professionals, we remind readers that Medicare regulatory requirements allow for coverage and payment

of outpatient occupational and physical therapy services in §§ 410.59(a) and 410.60(a), respectively, only if they are furnished by OTs and their supervised OTAs or by PTs and their supervised PTAs to meet the requirements in 42 CFR part 484.

A. Valuation for Remote Physiologic Monitoring (RPM)

For CPT code 99091, we disagree with the RUC's recommendation of 0.70 work RVUs and proposed to maintain the current work RVU of 1.10 and the corresponding physician time inputs. This code, as well as the other RPM codes, did not meet the minimum survey requirements established by the RUC for the January 2025 RUC meeting. The RPM coding will be resurveyed after 1 year of utilization data is available for this 2026 CPT code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately. The RUC did not recommend it, and we did not propose any direct PE inputs for CPT code 99091.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters were generally supportive of our proposal to maintain the work RVU and the corresponding physician time inputs for CPT code 99091.

Response: We appreciate the commenters for their support. After consideration of public comments, we are finalizing as proposed.

For CPT code 99470, we disagreed with the RUC's recommendation of 0.39 work RVUs and proposed a work RVU of 0.31, with 10 minutes or intraservice/total time. We disagreed with the recommended value and proposed a work RVU of 0.31 for CPT code 99470 based on the total time ratio between the 20 minutes of total time assigned to CPT code 99457 and the 10 minutes of total time assigned to CPT code 99470. This ratio equals 50 percent, and 50 percent of the current work RVU of 0.61 rounds to a work RVU of 0.31. Although we do not believe that the decrease in time described in the code descriptor must equate to a one-to-one or linear decrease in the valuation of work RVUs, since the two components of work are time and intensity, significant reductions in time for codes with equivalent intensity should generally be reflected in decreases to work RVUs. In the case of CPT code 99470, we believe it would be more accurate to propose the total time ratio at a work RVU of 0.31 to account for these decreases in work time compared to CPT code 99457. We also proposed using this time ratio with

the current PE inputs for CPT code 99457 for clinical staff time. We proposed 5 minutes of CA021 intraservice clinical labor time and 15 minutes of CA037 post-service clinical labor time for CPT code 99470.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters had mixed views on our proposed refinements to CPT code 99470. While some commenters supported our proposal, many commenters did not support the proposal based on the time ratio compared to CPT code 99457, as the RPM platform and staffing expense is fixed and does not decrease based on minutes of treatment management services provided. Many commenters requested that CMS finalize the RUC recommendations or align all the direct PE inputs with CPT code 99457.

Response: We continue to believe that since the two components of work are time and intensity, significant reductions in time for codes with equivalent intensity should generally be reflected in decreases to work RVUs. Although commenters pointed out that RPM platform and staffing expenses are fixed, there are no RPM platform-related inputs in CPT codes 99457 or 99470. The only PE input for these codes are clinical staff time, which does change based on the minutes of treatment management services provided.

After consideration of public comments, we are finalizing as proposed.

For CPT code 99457, we disagreed with the RUC's recommendation of 0.45 work RVUs and proposed to maintain the current work RVU of 0.61, the current work time of 20 minutes, and the current direct PE inputs. This code, as well as the other RPM codes, did not meet the minimum survey requirements established by the RUC for the January 2025 RUC meeting. RPM coding will be resurveyed after 1 year of utilization data is available for this 2026 CPT code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately. For CPT code 99458, we disagreed with the RUC's recommended direct PE inputs and proposed to maintain the current inputs. We proposed the RUC-recommended work RVU of 0.61 for CPT code 99458, as this work RVU was reviewed by the RUC and resulted in no recommended changes for CY 2026. Our proposal to maintain current work RVUs and PE inputs was due to the lack of survey data supporting changes to these codes' valuation, as none of the RPM codes met the minimum survey requirements

established by the RUC for the January 2025 RUC meeting. We also believe it is important to maintain relativity between RPM and RTM codes describing equivalent amounts of treatment management time and effort.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the CMS proposal not to propose the RUC recommendation and maintain the current valuation for CPT code 99457. Commenters supported the proposed work RVU of 0.61 for CPT code 99458, as this work RVU was reviewed by the RUC and resulted in no recommended changes for CY 2026. A few commenters requested that CMS require 16 to 30 days of data (CPT code 99454) to be collected to bill for additional treatment management services (CPT code 99458).

Response: We appreciate the commenters for their support for our proposal for CPT codes 99457 and 99458. While we understand that additional treatment management time may be less common for beneficiaries with fewer days of data collection, we do not believe it is necessary at this time to restrict treatment management services based on days of data collection. We will monitor these concerns by monitoring claims data and may address them in future rulemaking if needed.

After consideration of public comments, we are finalizing as proposed.

For CPT code 99474, we proposed the RUC-recommended work RVU of 0.18 and direct PE inputs without refinement, as this code was reviewed by the RUC and resulted in no recommended changes for CY 2026.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposals for CPT code 99474.

Response: We appreciate the commenters for their support.

After consideration of public comments, we are finalizing as proposed.

For CPT code 99473, which is a PE-only code, we proposed the RUC-recommended direct PE inputs without refinement, as this code was reviewed by the RUC and resulted in no recommended changes for CY 2026.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported CMS' proposals for CPT code 99473.

Response: We appreciate the commenters for their support.

After consideration of public comments, we are finalizing as proposed.

For CPT code 99453, which is a PE-only code, we proposed the RUC-recommended PE inputs without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposals for CPT code 99453. Commenters also requested clarification that CMS will adopt parenthetical changes for this code, specifically the requirement that this service now requires 2 days of monitoring in a 30-day period for reporting, as opposed to 16.

Response: We appreciate the commenters for their support. We will be adopting all descriptors, guidelines, prefatory language, and parenthetical changes made to the Remote Monitoring section of the 2026 edition of the CPT codebook, including for CPT code 99453.

After consideration of public comments, we are finalizing as proposed.

For the PE-only CPT codes 99445 and 99454, the RUC's recommendations included a "digital remote physiologic monitoring device app," which is a per-click vendor fee that has not traditionally been included as a form of direct PE. We understand that as these technologies evolve, the issues involving the use of software and other forms of digital tools become more difficult to account for accurately in our standard PE methodology. We acknowledge that for CPT codes 99445 and 99454, the overall payment rate is driven by practice expense supply and equipment inputs rather than physician work or clinical staff time We have concerns with the RUC-recommended PE inputs for device supply and equipment, as these inputs are difficult to accurately account for due to lack of substantive invoices and other types of supportive data. As MedPAC noted in their comment to the CY 2011 PFS proposed rule, "using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers may not result in objective and accurate prices because each group has a financial stake in the

process". We have repeatedly stated, such as in the CY 2018 final rule, that "we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs" (82 FR 52998). Given our concerns with the RUC-recommended direct PE inputs and our inability to verify the pricing for these inputs, we believe that using Hospital Outpatient Prospective Payment System (OPPS) cost data to value CPT codes 99445 and 99454 may more accurately reflect the actual costs of these technologies. We assume the costs incurred in furnishing these PE-only codes would be the same across settings of care (physician office and hospital outpatient), since these codes do not have any physician work and only account for PE associated with device supply and data transmission. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. We proposed to use OPPS cost data to establish the valuation for the practice expense portion of Remote Physiologic Monitoring CPT codes 99445 and 99454. We believe that the OPPS cost data is more accurate than the direct PE inputs recommended by the RUC. OPPS practice expense data obtained from cost reports is regularly updated, auditable, and required to adhere to national standards for reporting. For example, in the CY 2015 PFS final rule (79 FR 67569), we noted that "routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year". We proposed to utilize the OPPS total geometric mean cost for CPT code 99454 to inform the valuation of CPT codes 99445 and 99454 when paid under the PFS. We proposed to calculate this value by dividing the OPPS Geometric Mean Cost (GMC) for CPT code 99454, which is represented in a dollar amount, by the estimated CY 2026 PFS conversion factor (CF), which represents the dollar value of an RVU, in order to convert the GMC dollar amount into RVUs. The resulting value will be the PE RVU for CPT codes 99445 and 99454. We proposed the same valuation for both CPT codes 99445 and 99454 since the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters had mixed support for CMS' proposal for the same valuation for CPT codes 99445 and 99454. The commenters who supported the proposal stated that this would reduce administrative burden and the risk of coding confusion. Some commenters supported the reasoning that the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted. We received confirmation of this information from practitioners who furnish RPM services and vendors who supply RPM devices, stating that this aligns the actual technology costs, as these costs are tied to the number of patients receiving these services in a given 30-day period, not the number of days of data collected in those 30 days. The commenters who supported this proposal stated that the proposed valuation more accurately represents the reality of practice expense for these services. Commenters who did not support this proposal stated that a lower valuation for CPT code 99445 would pay for the actual use of the equipment and allow CMS to further ensure program integrity by accurately tracking spending. These commenters also believe that a lower valuation for CPT code 99445 would also incentivize more days of data collection, which would provide more value when determining a plan of care and reward adherence.

Response: We appreciate the commenters for this feedback on our proposal. With the additional information provided by commenters, we continue to believe that practice expense costs for these services remain the same, regardless of the number of days of data collected. We will continue to look into OPPS hospital cost reporting data and may consider changes for future rulemaking.

Comment: Several commenters appreciated the proposal to utilize OPPS data due to PE inputs that have not traditionally been included as a form of direct PE. Many commenters requested additional clarification and additional information on why CMS believes this data is more accurate. The commenters requested that CMS provide detailed data on how PE RVU inputs were derived from OPPS claims. Some commenters did not support the proposal to utilize OPPS data to value these services, as there are different statutory frameworks for payment under OPPS and PFS. Other commenters who did not support the proposal suggested that CMS value these services based on supplier invoices, not OPPS data.

Response: We appreciate the commenters for their support of our proposal to use OPPS data. As we stated in the proposed rule, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. Although the use of invoice data may be beneficial when valuing certain services, exclusively using invoices for the valuation of these PE-only services may not result in objective and accurate prices because each interested party that submits invoices has a financial stake in the process. By using OPPS practice expense data, we have built in guardrails since the data obtained from cost reports is regularly updated, auditable, and required to adhere to national standards for reporting.

Comment: Many commenters did not believe that the use of OPPS data was appropriate for these services when paid under the PFS, as the PE costs incurred in furnishing these services may not be the same across physician office and hospital outpatient settings of care. Commenters were concerned that the correlation between OPPS costs and physician costs has not been established. Also, the commenters stated that physician offices operate on less favorable economies of scale than hospital outpatient departments, and using OPPS data assumes hospital-level infrastructure, purchasing power, and cost-sharing that do not equate to those of physician offices. Commenters cautioned against direct reliance on OPPS data for PE valuation without adjustments, as hospital outpatient departments and physician offices operate under different cost structures and suggested an adjusted PE methodology for physicians and private practices as compared to larger health systems and corporations. Commenters also suggested that CMS incorporate site-neutral adjustment factors when using OPPS data to establish PE relativity. Commenters were concerned that directly transferring costs data between payment systems could potentially lead to inaccurate valuations and that using hospital cost data may lead to overpayments. Other commenters were concerned that hospital cost reports represent bundled purchasing arrangements that do not capture specific device costs, which may not be available to physician offices.

However, some commenters believe that the input costs incurred in furnishing PE-only device supply codes are the same across settings of care.

Response: We continue to believe that the costs incurred in furnishing these PE-only codes would be the same across settings of care (physician office and hospital outpatient), since these codes do not

have any physician work and only account for PE associated with device supply and data transmission. We welcome additional forms of data to assist us in refining PE methodology for future rulemaking.

Comment: Many commenters noted difficulty understanding CMS' proposal to use OPPS cost data to value CPT codes 99445 and 99454. Many commenters pointed out that the payment rates for CPT codes 99453 and 99454 under the OPPS differ drastically from the proposed PFS payment rates.

Response: Under the OPPS, we calculate a geometric mean cost for HCPCS codes paid under the OPPS. HCPCS codes are assigned to APCs using clinical criteria and geometric mean cost data. While we proposed to value the PE-only device supply codes using the OPPS cost data, we proposed the RUC-recommended direct PE inputs for CPT code 99453. We consider comments related to the OPPS payment rate for CPT code 99453 to be out of the scope of the proposed rule. Regarding the differing payment amounts for CPT code 99454 under the PFS and OPPS, we note that given that the APC payment rates are calculated using a system of averages, the geometric mean cost for HCPCS codes will often differ from the geometric mean cost for all services assigned to the APC. Differences in the payment systems explain the 20 percent difference in the proposed payment rate for CPT code 99454 under the PFS and the OPPS, since the PFS is using GMC to inform the valuation of CPT code 99454.

Comment: Several commenters requested more information about how the use of OPPS data will be updated over time and how the use of OPPS data will impact reimbursement. Commenters requested that, if finalized, CMS utilize OPPS data as an interim measure until updating the PE methodology to account for inputs associated with technology and digital platforms, such as subscription, data storage, and cybersecurity costs. Commenters also requested that CMS utilize the 2026 GMC for remote monitoring services, as finalized in the CY 2026 OPPS. Commenters requested that, if use of the 2026 GMC is finalized, this value remains static until the PE methodology is updated and does not get updated based on subsequent GMC changes.

Response: We appreciate the commenters for their input on this issue. We believe that it would be appropriate to utilize the most up-to-date cost data by using the CY 2026 GMC values in our calculations for CPT codes 99445 and 99454. We agree with commenters that the use of OPPS data, where appropriate, is a potential solution to a much larger challenge within the current PE methodology. We are interested in feedback and additional data from interested parties that could assist us in improving PE

inputs and methodology for services that are primarily valued through technology costs for future rulemaking.

After consideration of public comments, we are finalizing calculating this value by dividing the CY 2026 OPPS Geometric Mean Cost (GMC) for CPT code 99454, which is represented in a dollar amount, by the CY 2026 non-qualifying APM PFS conversion factor (CF), which represents the dollar value of an RVU, to convert the GMC dollar amount into RVUs. The resulting value will be our finalized PE RVU for CPT codes 99445 and 99454.

B. Valuation for Remote Therapeutic Monitoring (RTM)

For CPT code 98979, we disagreed with the RUC's recommendation of 0.66 work RVUs and proposed a work RVU of 0.31, with 10 minutes or intraservice/total time. We proposed this work RVU for CPT code 98979 based on the total time ratio between CPT code 98980's time of 20 minutes and CPT code 98979's time of 10 minutes. This ratio equals 50 percent, and 50 percent of the current work RVU of 0.62 for CPT code 98980 equals a work RVU of 0.31 for CPT code 98979. Although we do not believe that the decrease in time described in the code descriptor must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant reductions in time for codes with equivalent intensity should generally be reflected in decreases to work RVUs. In the case of CPT code 98979, we believe it would be more accurate to propose the total time ratio at a work RVU of 0.31 to account for these decreases in work time compared to CPT code 98980. We also proposed using this time ratio with the current direct PE inputs for CPT code 98980. We are proposing 5 minutes of CA021 intraservice clinical labor time and 15 minutes of CA037 post-service clinical labor time for CPT code 98979. We proposed this clinical labor using the RN/LPN/MTA (L037D) blend as this has historically been the typical clinical labor type for remote therapeutic monitoring services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters had mixed views on the proposed refinements to CPT code 98979. While some commenters supported the proposal, many commenters did not support our proposal based on the time ratio compared to CPT code 98980, as they stated that the RTM platform and staffing

expense is fixed and does not decrease based on minutes of treatment management services. The commenters who did not support the proposal believe that there was strong relativity to the reference code. Many commenters requested that CMS finalize the RUC recommendations, including increased clinical labor and revision of the clinical labor type from RN/LPN/MTA to PTA.

Response: We continue to believe that since the two components of work are time and intensity, significant reductions in time for codes with equivalent intensity should generally be reflected in decreases to work RVUs. After reviewing Medicare claims data for this service, we continue to believe that clinical labor using the RN/LPN/MTA (L037D) blend is currently the typical clinical labor type for CPT codes 98980 and 98981, which we believe will also be the same for CPT code 98979.

After consideration of public comments, we are finalizing as proposed.

For CPT code 98980, we disagreed with the RUC's recommendation of 0.78 work RVUs and are proposing to maintain the current work RVU of 0.62, the current 20 minutes of intraservice/total work time, and the current direct PE inputs. For CPT code 98981, we disagreed with the RUC's recommendation of 0.70 work RVUs and proposed to maintain the current work RVU of 0.61 and the current direct PE inputs; the RUC recommended, and we are proposing to maintain the current 20 minutes of intraservice/total work time. These proposals were due to wanting to maintain relativity between RPM and RTM codes describing equivalent amounts of treatment management time and effort. RTM coding will be placed on the New Technology list to be reviewed after 3 years of data are available for this CPT 2026 code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS finalize the RUC recommendations, including increased clinical labor and revision of the clinical labor type from RN/LPN/MTA to PTA. Some commenters did not support the proposal to maintain relativity with RPM codes, since this survey data showed growth in provider experience of furnishing RTM services. Commenters specified that therapists now have more experience with RTM services and can more accurately answer surveys than when the codes were created.

Response: We appreciate the commenters for their feedback. After reviewing Medicare claims data for this service, we continue to believe that clinical labor using the RN/LPN/MTA (L037D) blend is currently the typical clinical labor type for CPT codes 98980 and 98981. We continue to believe that it is important to maintain relativity between RPM and RTM treatment management services.

After consideration of public comments, we are finalizing as proposed.

For the PE-only CPT code 98975, the RUC's recommendations include a "Remote musculoskeletal therapy monitoring program enrollment fee." We did not propose a price for this input at this time as we believe this type of fee has not traditionally been included as a form of direct PE and would constitute forms of indirect PE under our methodology. We understand that as the PE data age, these issues involving the use of software and other forms of digital tools become more complex. However, in general we believe that this type of cost is most similar to indirect PE costs rather than direct costs, which must be individually allocable to a particular patient for a particular service. Additionally, we believe that indirect technology costs associated with RTM are better accounted for in the data transmission RTM codes (CPT codes 98985 and 98977, discussed below) that will also be reported during the beneficiary's course of treatment. We look forward to continuing to seek out new data sources to help in updating the PE methodology. The RTM coding will be placed on the New Technology list to be reviewed after 3 years of data are available for this 2026 CPT code structure, and we look forward to reviewing the additional data at that time to refine the valuation for this code more accurately. We proposed to maintain the current direct PE inputs for CPT code 98975.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters generally did not support CMS' proposals for CPT code 98975, specifically not proposing the RUC's recommended changes to the clinical labor type and the program enrollment fee for CPT code 98975. Commenters also requested clarification that CMS will adopt the parenthetical changes for this code, specifically the requirement that this service now requires 2 days of monitoring in a 30-day period for reporting, as opposed to 16.

Response: We appreciate the commenters for their feedback. The RUC recommended "Remote musculoskeletal therapy monitoring program enrollment fee" does not constitute a form of direct PE

under our methodology. After reviewing Medicare claims data for this service, we are not finalizing our proposal to retain the current clinical labor type, as physical therapists are currently the dominant specialty that furnishes this service, and the PTA (L039B) blend is the typical clinical labor type. We will be adopting all descriptors, guidelines, prefatory language, and parenthetical changes made to the Remote Monitoring section of the 2026 edition of the CPT codebook, including for CPT code 98975.

After consideration of public comments, we are finalizing as proposed, with the exception of revising the clinical staff type to PTA from RN/LPN/MTA.

For the PE-only CPT codes 98985 and 98977, the RUC's recommendations included a "Remote musculoskeletal therapy monitoring monthly supply fee," which is a per-click vendor fee that has not traditionally been included as a form of direct PE. We understand that as these technologies evolve, the issues involving the use of software and other forms of digital tools become more difficult to account for accurately in our standard PE methodology. We acknowledge that for CPT codes 98985 and 98977, the overall payment rate is driven by practice expense supply and equipment inputs rather than physician work or clinical staff time. We have concerns with the RUC-recommended PE inputs for device supply and equipment, as these inputs are difficult to accurately account for due to lack of substantive invoices and other types of supportive data. As MedPAC noted in their comment to the CY 2011 PFS proposed rule, "using price information voluntarily submitted by specialty societies, individual practitioners, suppliers, and product developers may not result in objective and accurate prices because each group has a financial stake in the process". We have repeatedly stated, such as in the CY 2018 final rule, that "we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical resource costs and create the potential for overestimation of supply and equipment costs" (82 FR 52998). Given our concerns with the RUC-recommended PE inputs and our inability to verify the pricing for these inputs, we believe that using Hospital Outpatient Prospective Payment System (OPPS) cost data to value CPT codes 98985 and 98977 may more accurately reflect the actual costs of these technologies as opposed to the PE inputs as recommended by the AMA RUC. We assume the costs incurred in furnishing these PE-only codes would be the same across settings of care (physician office and hospital outpatient), since these codes do not have any physician work and only account for PE associated with device supply and data transmission. Under section 1848(c)(2)(N) of the Act, we have authority to establish or adjust PE

RVUs using cost, charge, or other data from suppliers or providers of services. We proposed to use OPPS cost data to establish the valuation for the practice expense portion of Remote Therapeutic Monitoring CPT codes 98985 and 98977. We believe that the OPPS cost data is more accurate than the PE inputs recommended by the RUC. OPPS practice expense data obtained from cost reports is regularly updated, auditable, and required to adhere to national standards for reporting. For example, in the CY 2015 PFS final rule (79 FR 67569), we noted that "routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year". We proposed to utilize the OPPS total geometric mean cost for CPT code 98977 to inform the valuation of CPT codes 98985 and 98977 when paid under the PFS. We proposed to calculate this value by dividing the OPPS Geometric Mean Cost (GMC) for CPT code 98977, which is represented in a dollar amount, by the estimated CY 2025 PFS conversion factor (CF), which represents the dollar value of an RVU, in order to convert the GMC dollar amount into RVUs. The resulting value will be our proposed PE RVU for CPT codes 98985 and 98977. We proposed the same valuation for both CPT codes 98985 and 98977 since the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted.

We also proposed to maintain the current clinical staff type for the RTM codes (RN/LPN/MTA), as opposed to the RUC recommendation of physical therapy assistant, since the dominant specialty type that bills this code, family medicine, did not participate in the survey.

We solicited comments specifically on data to support the recommended PE inputs for this code, including invoices, additional data, or evidence to support the position. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters had mixed support for CMS' proposal for the same valuation for CPT codes 98985 and 98977. The commenters who supported the proposal stated that this would reduce administrative burden and the risk of coding confusion. Some commenters supported the reasoning that the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that

data is transmitted. We received confirmation of this information from practitioners who furnish RTM services and vendors who supply RTM devices, stating that this aligns the actual technology costs, as these costs are tied to the number of patients receiving these services in a given 30-day period, not the number of days of data collected in those 30 days. Commenters who supported this proposal stated that the proposed valuation more accurately represents the reality of practice expense for these services. Commenters who did not support this proposal stated that a lower valuation for CPT code 98985 would pay for the actual use of the equipment and allow CMS to further ensure program integrity by accurately tracking spending. These commenters also believe that a lower valuation for CPT code 98985 would also incentivize more days of data collection, which would provide more value when determining a plan of care and reward adherence.

Response: We appreciate the commenters for this feedback on our proposal. With the additional information provided by commenters, we continue to believe that practice expense costs for these services remain the same, regardless of the number of days of data collected. We will continue to look into OPPS hospital cost reporting data and other forms of data and may consider changes for future rulemaking.

Comment: Several commenters appreciated CMS' proposal to utilize OPPS data due to PE inputs that have not traditionally been included as a form of direct PE. Many commenters requested additional clarification and additional information on why CMS believes this data is more accurate. The commenters requested that CMS provide detailed data on how PE RVU inputs were derived from OPPS claims. Some commenters did not support the proposal to utilize OPPS data to value these services, as there are different statutory frameworks for payment under OPPS and PFS. Other commenters who did not support the proposal suggested that CMS value these services based on supplier invoices, not OPPS data.

Response: We appreciate the commenters for their support of our proposal to use OPPS data. As we stated in the proposed rule, we have authority to establish or adjust PE RVUs using cost, charge, or other data from suppliers or providers of services. Although the use of invoice data may be beneficial when valuing certain services, exclusively using invoices for the valuation of these PE-only services may not result in objective and accurate prices because each interested party that submits invoices has a financial stake in the process. By using OPPS practice expense data, we have built in guardrails since the data obtained from cost reports is regularly updated, auditable, and required to adhere to national

standards for reporting. We note that we did not develop direct PE inputs for these services from OPPS claims. We proposed to calculate the PE RVU by dividing the OPPS Geometric Mean Cost (GMC) for CPT code 98977, which is represented in a dollar amount, by the estimated CY 2025 PFS conversion factor (CF), which represents the dollar value of an RVU, in order to convert the GMC dollar amount into RVUs. The resulting value was our proposed PE RVU for CPT codes 98985 and 98977. There are no separate PE inputs for these services outside of this RVU calculation.

Comment: Many commenters did not believe that the use of OPPS data was appropriate for these services when paid under the PFS, as the PE costs incurred in furnishing these services may not be the same across physician office and hospital outpatient settings of care. Commenters were concerned that the correlation between OPPS costs and physician costs has not been established. Commenters cautioned against direct reliance on OPPS data for PE valuation without adjustments, as physician offices operate on less favorable economies of scale than hospital outpatient departments, and using OPPS data assumes hospital-level infrastructure, purchasing power, and cost-sharing that do not equate to physician offices, and suggested an adjusted PE methodology for physicians and private practices as compared to larger health systems and corporations. Commenters also suggested that CMS incorporate site-neutral adjustment factors when using OPPS data to establish PE relativity. Commenters were concerned that directly transferring costs data between payment systems could potentially lead to inaccurate valuations and that using hospital cost data may lead to overpayments. Other commenters were concerned that hospital cost reports represent bundled purchasing arrangements that do not capture specific device costs, which may not be available to physician offices.

A few commenters also believe that since CPT code 98977 requires using Food and Drug Administration (FDA)-regulated medical devices, which involve higher costs than non-device, app-only alternatives, using OPPS cost data would not appropriately reflect the costs of furnishing this service.

However, some commenters believe that the input costs incurred in furnishing PE-only device supply codes were the same across settings of care.

Response: We continue to believe that the costs incurred in furnishing these PE-only codes would be the same across settings of care (physician office and hospital outpatient), since these codes do not

have any physician work and only account for PE associated with device supply and data transmission. We welcome additional forms of data to assist us in refining the PE methodology for future rulemaking.

Comment: We received many comments confusing the OPPS cost data CMS proposed to use to value CPT codes 98985 and 98977. Many commenters pointed out that the payment rates for remote monitoring services using Ambulatory Payment Classifications under the OPPS differ drastically from the current and RUC-recommended payment rates for the PFS.

Response: Under the OPPS, we calculate a geometric mean cost for HCPCS codes paid under the OPPS. HCPCS codes are assigned to APCs using clinical criteria and geometric mean cost data. We would like to clarify that our proposal for using OPPS cost data to inform the valuation of CPT codes 98985 and 98977 is using the Geometric Mean Cost (GMC) from the OPPS, not the Ambulatory Payment Classifications (APC).

Comment: A commenter requested that, since CPT code 98977 has limited OPPS cost-reporting, CMS should utilize the more frequently reported cost-reporting for CPT code 99454 to inform the PFS valuation for CPT codes 98985 and 98977. The commenter stated that this would align with CMS' proposal to maintain relativity between RPM and RTM services, since PE costs for these services are similar.

Response: We appreciate the additional information provided around the use of the OPPS GMC to inform the valuation of CPT codes 98985 and 98977. We believe that it would be appropriate to utilize the most up-to-date cost data by using the CY 2026 GMC value for CPT code 98977 in our calculations for CPT codes 98985 and 98977. The CY 2026 GMC values are more comparable than the CY 2025 GMC values used to inform the valuation of these services in the PFS proposed rule and will assist in maintaining relativity between RPM and RTM.

Comment: Commenters requested more information about how the use of OPPS data will be updated over time and how the use of OPPS data will impact reimbursement. Commenters requested that, if finalized, CMS utilize OPPS data as an interim measure until we update PE methodology to account for inputs associated with technology and digital platforms, such as subscription, data storage, and cybersecurity costs. Commenters also requested that CMS utilize the 2026 GMC for remote monitoring services, as finalized in the CY 2026 OPPS. Commenters requested that, if use of the 2026 GMC is

finalized, this value remain static until PE methodology is updated and does not get updated based on subsequent GMC changes.

Response: We appreciate commenters for their input on this issue. We believe that it would be appropriate to utilize the most up-to-date cost data by using the CY 2026 GMC values in our calculations for CPT codes 98985 and 98977. We agree with commenters that the use of OPPS data, where appropriate, is a potential solution to a much larger challenge within the current PE methodology. We are interested in feedback and additional data from interested parties that could assist us in improving PE inputs and methodology for services that are primarily valued through technology costs for future rulemaking.

After consideration of public comments, we are finalizing calculating this value by dividing the CY 2026 OPPS Geometric Mean Cost (GMC) for CPT code 98977, which is represented in a dollar amount, by the CY 2026 non-qualifying APM PFS conversion factor (CF), which represents the dollar value of an RVU, to convert the GMC dollar amount into RVUs. The resulting value will be our finalized PE RVU for CPT codes 98985 and 98977.

The RUC recommended and CMS proposed to contractor price the PE-only CPT codes 98984 and 98976.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters did not support CMS' proposal to contractor price CPT codes 98984 and 98976. The commenters suggested CMS retain the current active pricing for these codes as finalized in the CY 2022 PFS final rule.

Response: We appreciate the commenters for their input. In the CY 2022 PFS final rule, we finalized actively pricing CPT code 98976 by crosswalking to the PE RVU for comparable RPM CPT code 99454, since that code includes payment for the device used to collect and transmit data. We agree with commenters that this crosswalk methodology would still be appropriate to value CPT code 98976. We are finalizing the same valuation for CPT codes 99445 and 99454, since the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted, and more accurately represents the reality of practice expense for these services. We believe the same coding

structure exists with CPT codes 98976 and 98984 and believe that using the same valuation for both codes would be appropriate.

After consideration of public comments, we are finalizing actively pricing CPT codes 98976 and 98984 by crosswalking the PE RVU to CPT code 99454.

CPT codes 98986 and 98978 are PE-only codes. We proposed to contractor price CPT code 98986 and proposed to maintain contractor pricing for CPT code 98978.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support CMS' proposal to contractor price CPT codes 98986 and 98978. Many commenters requested these codes be actively priced and finalize the RUC recommendation for the device supply. Commenters requested that CMS crosswalk these codes to CPT codes 98976 and 98977. Commenters requested that CMS actively price these codes and review them in the future after more data is collected. A few commenters did not support payment under the PFS for these services, as they believe that there is limited evidence that CBT RTM services will meaningfully improve clinical outcomes and that utilization of these services may reduce direct clinical time that patients receive.

Response: We continue to believe that the technologies for this service are still evolving and there is significant pricing variability for these technologies. We will continue to work with our Medicare Administrative Contractors (MACs) to better understand the kinds of devices and device costs they are encountering as they review claims for payment.

After consideration of public comments, we are finalizing as proposed.

C. Comment Solicitation

We solicited comments on whether there are differences in the valuation of remote physiologic and remote therapeutic monitoring, specifically whether the services have similar costs and/or practice expense inputs. We proposed similar valuations for what we have historically viewed as similar remote monitoring services (for example, RTM and RPM treatment management, RTM and RPM device supply, RTM and RPM data transmission), but we were interested in gaining more information regarding any differences in work (in the case of timed codes, if there are varying levels of intensity between remote

therapeutic vs. physiologic monitoring), clinical staff time, supplies, equipment, etc. We were particularly interested in comments that include data or evidence to support the position.

Comment: Several commenters had mixed views on whether there are differences in the valuation of remote physiologic and remote therapeutic monitoring. Commenters who believe these services were similar stated that equal valuation of RTM and RPM codes will promote consistency and fairness in reimbursement and support broader adoption of remote monitoring services. These commenters also believe that clinical workflows, physician oversight, and labor requirements are essentially identical across both service types. Commenters who believe the services were similar were concerned that one service being valued higher than the other would discourage use of the service. Commenters who believe these services do not have similar valuation believe so due to different clinical use cases, the evolving nature of the technologies involved, and the relatively new nature of RTM coverage. A few commenters requested that CMS extend relativity between RTM and RPM codes to all codes within these code families, such as the device supply codes.

Response: We appreciate the commenters for providing further information about the differences in remote physiologic and remote therapeutic monitoring, and how these services could be improved in the future. We will consider this information for future rulemaking.

(33) Hearing Device Services (CPT codes 92628, 92629, 92631, 92632, 92634, 92635, 92636, 92637, 92638, 92639, 92641, and 92642).

At the February 2024 CPT Editorial Panel meeting, 12 new Category I codes were created to report hearing devices services (for example, air-conduction hearing aids) including hearing aid candidacy determination, hearing aid selection, hearing aid fitting, follow-up after fitting, hearing aid verification, and assistive-device services. The current CPT codes, 92590-92595, were recommended for deletion. CPT codes 92628-92642 were reviewed at the April 2024 RUC HCPAC meeting for CY 2026.

The following is a list of the new CPT codes and their long descriptors: CPT code 92628 (*Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (for example, speech-in-noise, suprathreshold hearing measures) discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; first 30 minutes*), CPT

code 92629 (*Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (for example, speech-in-noise, suprathreshold hearing measures) discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; each additional 15 minutes*), CPT code 92631 (*Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; first 30 minutes*), CPT code 92632 (*Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; each additional 15 minutes*), CPT code 92634 (*Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; first 60 minutes*), CPT code 92635 (*Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes*), CPT code 92636 (*Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (for example, verification, programming adjustment(s), device connection(s), and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; first 30 minutes*), CPT code 92637 (*Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (for example, verification, programming adjustment(s), device connection(s), and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes*), CPT code 92638 (*Behavioral verification of amplification including aided thresholds, functional gain, speech in noise, when performed*), CPT code 92639 (*Hearing-aid*

measurement, verification with probe-microphone), CPT code 92641 (*Hearing device verification, electroacoustic analysis*), and CPT code 92642 (*Hearing assistive device, supplemental technology fitting services (for example, personal frequency modulation (FM)/ digital modulation (DM) system, remote microphone, alerting devices)*).

The RUC is recommending contractor pricing for all twelve codes in the family. However, section 1862(a)(7) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for hearing aids or examinations therefore, it has been our established policy not to pay for these hearing device services on the PFS, as their predecessor CPT codes 92590-92595 all have non-payable status codes. Therefore, we proposed to maintain the same policy of assigning non-payable status codes to each of the twelve new CPT codes in this family.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that although they appreciated the opportunity to comment on the payment status of these codes, they disagreed with CMS' proposal to continue to assign non-payable status codes to each of these codes. Commenters stated that they had concerns with potential scope of practice limitations that may impact implementation, certain codes in the family contain services that are not suitable for pediatric cases, and the bundled codes pose challenges for documenting medical necessity. Some commenters suggested CMS to finalize contractor pricing for each of these codes, as the RUC recommended, while other commenters requested that CMS pause the deletion of CPT codes 92590-92595 and the implementation of CPT codes 92628-92641 until these potential issues could be addressed.

Response: As we stated in the proposed rule, section 1862(a)(7) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for hearing aids or examinations. We therefore continue to believe that the 12 new CPT codes in this family should maintain the same non-payable status as their predecessor codes. With regards to CPT codes 92590-92595, the CPT Editorial Panel will be deleting these codes for CY 2026 which is outside the control of CMS. We did not propose to maintain the current coding through the creation of G codes, as we believe that the new code set creates a more

granular structure to describe these services and which will maintain the same non-payable status under which the predecessor codes were valued.

Comment: Several commenters expressed concerns with provider education associated with the codes in this family. Commenters stated that the CY 2026 effective date may not provide sufficient time for health systems, commercial payers, and state Medicaid programs to update their systems to accommodate the new codes. Commenters stated that several of the new codes would benefit from greater specificity and clarification and expressed concerned about the time-based structure of certain codes which could allow for potential overlap between codes.

Response: We appreciate the concerns of the commenters with the need for provider education associated with these new codes, as well as their concerns with the structure of the coding as designed by the CPT Editorial Panel. However, these issues are outside the scope of this rule as we do not address provider education associated with new coding in the PFS final rule.

After consideration of the comments, we are finalizing our proposal to assign non-payable status codes to each of the twelve new CPT codes in this family.

(34) Scalp Cooling Services (CPT codes 97007, 97008, and 97009)

At the September 2024 CPT Editorial Panel meeting, CPT deleted two Category II CPT codes and created three new Category I CPT codes, CPT code 97007 (*Mechanical Scalp cooling, including individual cap supply with head measurement, fitting, and patient education)*, 97008 (*mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and pre-cooling period*), and 97009 (*mechanical scalp cooling; each 30 minutes*)) to report scalp cooling services to address chemotherapy induced alopecia. The new codes were surveyed for the January 2025 RUC meeting and the RUC determined that the code family requires no physician work and are practice expense (PE) only services. As such, the RUC did not recommend, and we are not proposing work RVUs for these codes.

We disagree with the RUC-recommended 5 minutes of service period clinical staff time in direct PE input CA021 (Perform procedure/service—not directly related to physician work time) for CPT code 97007. We proposed 27 minutes of clinical labor time for CA021 based off reference CPT code 99453 (*Remote monitoring of physiologic parameter(s) (for example, weight, blood pressure, pulse oximetry,*

respiratory flow rate), initial; set-up and patient education on use of equipment). We have received feedback from interested parties that 5 minutes does not adequately account for the full duration of time required to educate, measure, fit, and calibrate the cap. We agree with interested parties and believe that the 27 minutes of clinical staff time in CA021 for CPT code 99453 better accounts for the full duration of time required for this service. We are proposing all other direct PE inputs, supplies, and equipment as recommended by the RUC for CPT code 97007. We are also proposing all direct PE inputs, supplies, and equipment as recommended by the RUC for CPT codes 97008 and 97009 without refinement.

We received public comments on scalp cooling services. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the proposed direct PE inputs for CPT code 97007 and recommended that CMS finalize as proposed. Commenters stated that they appreciated CMS deviating from the RUC-recommended values for this code and the allotted additional clinical staff time for clinical activity CA021.

Response: We appreciate the commenters for their support.

Comment: Several commenters disagreed with our proposed increase in clinical staff time for CPT code 97007 and requested that CMS finalize the RUC-recommendations for this code. Commenters stated that this portion of clinical staff work, which CMS increased to 27 minutes based off reference CPT code 99453, is more complex for the reference code than the setup and patient education required in CPT code 97007 since the reference code requires the explanation of outputs and obtaining the initial readings for the remote physiologic device. The cap for scalp cooling does not require any data elements to be processed and recorded by the patient for CPT code 97007 and therefore would only require 5 minutes for CA021 as recommended by the RUC.

Response: We acknowledge the commenters' feedback. However, we continue to believe that our proposed increase in CA021 clinical staff time for CPT code 97007 is appropriate for the required clinical activities during this portion of the scalp cooling service. We stated in the proposed rule that this additional clinical staff time better accounts for the full duration of time required to educate, measure, fit, and calibrate the cap, as suggested initially by interested parties and then repeated again by commenters.

Based on the additional information that we have received on this topic, we do not believe that these tasks could typically be carried out in 5 minutes as recommended by the RUC.

Comment: Several commenters disagreed with the proposed direct PE inputs for all the codes in this family. The commenters requested CMS to increase the direct PE inputs for CPT code 97007 from the proposed 36 total clinical staff minutes to 103 total clinical staff minutes. Commenters also requested an increase in total clinical staff minutes for CPT code 97008 from the RUC-recommended value of 9 minutes to 52 minutes with the addition of the following equipment items: scalp cooling system and a medical recliner chair (EF009) for 30 minutes. For CPT code 97009, commenters requested an increase in total clinical staff minutes from the RUC-recommended value of 6 minutes to 23 minutes and the same equipment items: scalp cooling system and a medical recliner chair (EF009) for 30 minutes. The commenters stated that this service utilizes infusion center resources for lengthy periods of time and that the requested clinical staff times are based on a time and motion study of 10 cancer centers; commenters disagreed with the RUC-recommended values and believe that the RUC did not include all necessary resources and were under-reported. Commenters also had concerns regarding equity and access for this service and requested that CMS set the medically unlikely edits for CPT code 97009 to 6.

Response: We acknowledge commenters' request for additional clinical staff time for all the codes in this family as well as additional equipment for CPT codes 97008 and 97009. We also acknowledge that the commenters are basing this request from a time and motion study that they are relying on to be an additional data source beyond the RUC review process to validate their request. We are interested in and open to alternate data sources other than the RUC review and survey process when making valuation decisions for CPT codes. However, for this code family, we continue to believe that the proposed clinical staff time for CPT code 97007 sufficiently accounts for the clinical activities of cap fitting and calibration and patient education. We also continue to believe that the RUC-recommended direct PE inputs sufficiently account for the clinical activities described in CPT code 97008 and 97009.

For the requested equipment item, the medical recliner chair (EF009), 60 minutes of time is included for the chemotherapy infusion codes, such as CPT code 96365 (*Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour*) and CPT code 96366 (*Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional*

hour (List separately in addition to code for primary procedure)), which would be billed during the same patient encounter and account for portions of the time in the chair used by the patient. We agree with commenters that this does not account for the full time in the medical recliner chair for each chemotherapy with scalp cooling service session. Therefore, we are adding 30 minutes of equipment time for the medical recliner chair (EF009) for CPT code 97008 and 97009.

For the scalp system coolant, we did not receive any RUC-recommendations for the system equipment and interested parties have reported that the system is leased equipment and could be shared by multiple patients. As such, we believe that this cost can be accurately captured with our indirect PE methodology. We acknowledge commenters' concerns regarding access to this service and are open to further discussions in the future. The request for medically unlikely edits is out of scope for the PFS rule but can be addressed via the National Correct Coding Initiative (https://www.cms.gov/national-correct-coding-initiative-ncci).

After consideration of the public comments, we are finalizing the direct PE inputs for the scalp cooling services as proposed, with the addition of 30 minutes of equipment time for the medical recliner chair in CPT codes 97008 and 97009. We did not propose, and we are not finalizing a work RVU for the three codes in this family.

TABLE A-E12: CY 2026 WORK RVUs FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia	C	C	2.70	Yes
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	C	2.43	2.43	No
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	C	1.05	1.05	No
0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	C	C	0.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
27458	Osteotomy(ies), femur, unilateral, with insertion of an externally controlled intramedullary lengthening device, including iliotibial band release when performed, imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NEW	26.65	26.65	No
27465	Osteoplasty, femur; shortening	18.60	21.13	21.13	No
27466	Osteoplasty, femur; lengthening	17.28	22.65	22.65	No
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	19.97	19.97	D	Yes
27713	Osteotomy(ies), tibia, including fibula when performed, unilateral, with insertion of an externally controlled intramedullary lengthening device, including imaging, alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NEW	28.00	28.00	No
27715	Osteoplasty, tibia and fibula, lengthening or shortening	15.50	22.50	22.50	No
28750	Arthrodesis, great toe; metatarsophalangeal joint	8.57	8.75	8.75	No
28755	Arthrodesis, great toe; interphalangeal joint	4.88	6.76	7.50	No
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	14.00	10.25	10.25	No
33880	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft covering the left subclavian artery and all aortic tube endograft extension(s) proximally in the aortic arch and ascending aorta and distally to the celiac artery, when performed	34.58	27.00	27.00	No
33881	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft not involving coverage of the left subclavian artery origin and all endograft extension(s) placed from the level of the left subclavian carotid artery to the celiac artery	29.58	22.53	22.53	No
33882	Endovascular repair of the thoracic aorta by deployment of a branched endograft multipiece system involving an aorto-aortic tube device with a fenestration for the left subclavian artery stentgraft(s) and all aortic tube endograft extension(s) placed from the level of the left common carotid artery to the celiac artery, including pre-procedure sizing and device selection, all target zone angioplasty, all nonselective catheterization(s) and left subclavian artery selective catheterization(s), and all associated radiological supervision and interpretation	NEW	35.00	35.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
33883	Delayed placement of proximal extension prosthesis(es) not involving coverage of the left subclavian artery origin, after endovascular repair of the thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed	21.09	19.91	19.91	No
33886	Delayed placement of distal extension prosthesis(es) from the level of the left subclavian artery to the celiac artery, after endovascular repair of descending thoracic aorta, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation	18.09	19.91	19.91	No
35602	Bypass graft, with other than vein; carotid-contralateral carotid	NEW	23.53	23.53	No
37254	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	7.30	7.30	No
37255	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No
37256	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	10.75	10.75	No
37257	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.89	3.89	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37258	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	8.75	8.75	No
37259	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37260	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	12.69	12.69	No
37261	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No
37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37263	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	7.75	7.75	No
37264	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No
37265	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	10.50	10.50	No
37266	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37267	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	8.75	8.75	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37268	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.73	3.73	No
37269	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	14.75	14.75	No
37270	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.00	5.00	No
37271	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	9.00	9.00	No
37272	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37273	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	12.63	12.63	No
37274	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.50	5.50	No
37275	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	11.00	11.00	No
37276	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37277	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	15.00	15.00	No
37278	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	6.00	6.00	No
37279	Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37280	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	9.80	9.80	No
37281	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.00	3.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37282	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	12.31	12.31	No
37283	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.26	4.26	No
37284	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	10.00	10.00	No
37285	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	3.34	3.34	No
37286	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	13.46	13.46	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37287	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.00	5.00	No
37288	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	13.50	13.50	No
37289	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.75	4.75	No
37290	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	17.00	17.00	No
37291	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	6.50	6.50	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37292	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel	NEW	15.00	15.00	No
37293	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	6.50	6.50	No
37294	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel	NEW	18.00	18.00	No
37295	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	8.16	8.16	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
37296	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel	NEW	11.00	11.00	No
37297	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	4.00	4.00	No
37298	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel	NEW	13.70	13.70	No
37299	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)	NEW	5.00	5.00	No
43889	Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed	NEW	12.56	12.56	No
47384	Ablation, irreversible electroporation, liver, 1 or more tumors, including imaging guidance, percutaneous	NEW	9.41	9.41	No
52443	Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a nondrug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed	NEW	3.62	3.62	No
52500	Transurethral resection of bladder neck (separate procedure)	8.14	6.00	6.00	No
52597	Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed	NEW	10.25	10.25	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	13.16	10.00	10.00	No
52630	Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	6.55	6.55	6.55	No
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	12.15	10.05	10.05	No
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	14.56	13.00	13.00	No
55705	Biopsy, prostate, any approach, nonimaging-guided	4.61	1.93	1.93	No
55706	Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance	6.28	4.27	4.27	No
55707	Biopsy, prostate, transrectal, ultrasound-guided (ie, sextant, ultrasound-localized discrete lesion[s])	NEW	2.63	2.63	No
55708	Biopsy, prostate, transrectal, ultrasound-guided (ie, sextant) with MRI-fusion-guidance, first targeted lesion	NEW	3.39	3.39	No
55709	Biopsy, prostate, transperineal, ultrasound-guided (ie, sextant, ultrasound-localized discrete lesion[s])	NEW	3.23	3.23	No
55710	Biopsy, prostate, transperineal, ultrasound-guided (ie, sextant) with MRI-fusion-guidance biopsy, first targeted lesion	NEW	3.81	3.81	No
55711	Biopsy, prostate, transrectal, MRI-ultrasound-fusion guided, targeted lesion(s) only, first targeted lesion	NEW	2.61	2.61	No
55712	Biopsy, prostate, transperineal, MRI-ultrasound-fusion guided, targeted lesion(s) only, first targeted lesion	NEW	3.10	3.10	No
55713	Biopsy, prostate, in-bore CT- or MRI-guided (ie, sextant), with biopsy of additional targeted lesion(s), first targeted lesion	NEW	4.00	4.00	No
55714	Biopsy, prostate, in-bore CT- or MRI-guided targeted lesion(s) only, first targeted lesion	NEW	3.62	3.62	No
55715	Biopsy, prostate, each additional, MRI-ultrasound fusion or in-bore CT- or MRI-guided targeted lesion (List separately in addition to code for primary procedure)	NEW	1.05	1.05	No
55840	Prostatectomy, retropubic radical, with or without nerve sparing;	21.36	21.36	21.36	No
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	21.36	21.36	21.36	No
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic	25.18	25.18	25.18	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
	lymphadenectomy, including external iliac, hypogastric, and obturator nodes				
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed;	22.46	22.46	22.46	No
55867	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed	19.53	19.53	19.53	No
55868	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with lymph node biopsy(ies) (limited pelvic lymphadenectomy)	NEW	22.46	22.46	No
55869	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	NEW	27.41	27.41	No
55877	Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous	NEW	13.50	13.50	No
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), including all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention, percutaneous, any method; central nervous system (intracranial, spinal cord)	20.12	17.06	20.00	No
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), including all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention, percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	16.60	13.46	15.31	No
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed	18.95	18.95	18.95	No
62330	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; one interspace, lumbar	NEW	8.00	8.00	No
62331	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
63032	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)	NEW	2.50	2.50	No
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation	NEW	1.50	1.50	No
64654	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	NEW	11.00	11.00	No
64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	NEW	11.30	11.30	No
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	NEW	8.01	8.01	No
64657	Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator	NEW	12.13	12.13	No
64658	Removal of baroreflex activation therapy (BAT) modulation system; lead only	NEW	8.95	8.95	No
64659	Removal of baroreflex activation therapy (BAT) modulation system; pulse generator only	NEW	8.23	8.23	No
64728	Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance	NEW	2.70	2.70	No
70471	Computed tomographic angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing	NEW	2.50	2.50	No
70472	Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)	NEW	0.77	0.77	No
70473	Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy	NEW	1.00	1.00	No
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	1.75	No
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	1.75	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
75577	Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified health care professional	NEW	0.85	0.85	No
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation	1.31	2.25	2.25	No
75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	1.65	1.85	1.85	No
76872	Ultrasound, transrectal;	0.69	0.67	0.67	No
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed	I	0.70	0.70	No
77402	Radiation treatment delivery; Level 1 (eg, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed	I	0.00	0.00	No
77407	Radiation treatment delivery; Level 2, single isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed	I	0.00	0.00	No
77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (eg, 2D, 3D, or IMRT) OR a single isocenter photon therapy (eg, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed	I	0.00	0.00	No
77417	Therapeutic radiology port image(s)	0.00	B	B	No
77436	Surface radiation therapy; superficial or orthovoltage, treatment planning and simulation-aided field setting	NEW	0.77	0.77	No
77437	Surface radiation therapy; superficial, delivery, ≤150 kV, per fraction (eg, electronic brachytherapy)	NEW	0.00	0.00	No
77438	Surface radiation therapy; orthovoltage, delivery, >150-500 kV, per fraction	NEW	0.00	0.00	No
77439	Surface radiation therapy; superficial or orthovoltage, image guidance, ultrasound for placement of radiation therapy fields for treatment of cutaneous tumors, per course of treatment (List separately in addition to code for primary procedure)	NEW	0.30	0.30	No
90480	Immunization administration by intramuscular injection, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine; first or only component of each vaccine administered	X	X	X	Yes
90481	Immunization administration by intramuscular injection, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine; each additional component administered (List separately in addition to code for primary procedure)	NEW	X	X	No
90482	Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; 3 minutes up to 10 minutes	NEW	I	I	No
90483	Immunization counseling by physician or other qualified health care professional when	NEW	I	I	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
	immunization(s) is not administered by provider on the same date of service; greater than 10 minutes up to 20 minutes				
90484	Immunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service; greater than 20 minutes	NEW	I	I	No
90832	Psychotherapy, 30 minutes with patient	1.86	1.94	1.94	No
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service	1.64	1.71	1.71	No
90834	Psychotherapy, 45 minutes with patient	2.45	2.56	2.56	No
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service	2.08	2.17	2.17	No
90837	Psychotherapy, 60 minutes with patient	3.63	3.78	3.78	No
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service	2.74	2.86	2.86	No
90839	Psychotherapy for crisis; first 60 minutes	3.43	3.58	3.58	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.64	1.71	1.71	No
90845	Psychoanalysis	2.30	2.40	2.40	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.63	2.74	2.74	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.74	2.86	2.86	No
90849	Multiple-family group psychotherapy	0.65	0.67	0.67	No
90853	Group psychotherapy (other than of a multiple-family group)	0.65	0.67	0.67	No
91124	Rectal sensation, tone, and compliance study (eg, barostat)	NEW	3.05	3.05	No
91125	Anorectal manometry, with rectal sensation and rectal balloon expulsion test, when performed	NEW	2.70	2.70	No
92284	Diagnostic dark adaptation examination (eg, rod and cone sensitivities, rod-cone breakpoint), with interpretation and report	0.00	0.29	0.29	No
92288	Screening dark adaptation measurement (eg, rod recovery intercept time), with interpretation and report	NEW	N	N	No
92628	Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (eg, speech-in-noise, suprathreshold hearing measures), discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; first 30 minutes	NEW	N	N	No
92629	Evaluation for hearing aid candidacy, unilateral or bilateral, including review and integration of audiologic function tests, assessment, and interpretation of hearing needs (eg, speech-in-noise, suprathreshold hearing measures), discussion of candidacy results, counseling on treatment options with report, and, when performed, assessment of cognitive and communication status; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	N	N	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
92631	Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; first 30 minutes	NEW	N	N	No
92632	Hearing aid selection services, unilateral or bilateral, including review of audiologic function tests and hearing aid candidacy evaluation, assessment of visual and dexterity limitations, and psychosocial factors, establishment of device type, output requirements, signal processing strategies and additional features, discussion of device recommendations with report; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	N	N	No
92634	Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; first 60 minutes	NEW	N	N	No
92635	Hearing aid fitting services, unilateral or bilateral, including device analysis, programming, verification, counseling, orientation, and training, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	N	N	No
92636	Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (eg, verification, programming adjustment[s], device connection[s], and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; first 30 minutes	NEW	N	N	No
92637	Hearing aid post-fitting follow-up services, unilateral or bilateral, including confirmation of physical fit, validation of patient benefit and performance, sound quality of device, adjustment(s) (eg, verification, programming adjustment[s], device connection[s], and device training), as indicated, and, when performed, hearing assistive device, supplemental technology fitting services; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	N	N	No
92638	Behavioral verification of amplification including aided thresholds, functional gain, speech in noise, when performed (List separately in addition to code for primary procedure)	NEW	N	N	No
92639	Hearing-aid measurement, verification with probe-microphone (List separately in addition to code for primary procedure)	NEW	N	N	No
92641	Hearing device verification, electroacoustic analysis	NEW	N	N	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
92642	Hearing assistive device, supplemental technology fitting services (eg, personal frequency modulation [FM]/digital modulation [DM] system, remote microphone, alerting devices)	NEW	N	N	No
92920	Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)	9.85	8.35	8.35	No
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)	11.74	10.13	10.13	No
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 1 lesion involving 1 or more coronary segments	10.96	10.00	10.00	No
92930	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 2 or more distinct coronary lesions with 2 or more coronary stents deployed in 2 or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch	NEW	12.00	12.00	No
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)	12.29	11.94	11.94	No
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed, single major coronary artery and/or its branches	10.95	11.30	11.30	No
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single major coronary artery and/or its branches or single bypass graft and/or its subtended branches	12.31	12.72	12.72	No
92943	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach	12.31	13.69	13.69	No
92945	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches	NEW	15.00	15.00	No
92973	Percutaneous transluminal coronary mechanical aspiration thrombectomy (List separately in addition to code for primary procedure)	3.28	1.75	1.75	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
93145	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming	NEW	0.65	0.65	No
93146	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming, including optimization of tolerated therapeutic level setting	NEW	0.90	0.90	No
93296	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	0.00	0.00	0.00	No
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; initial vessel (List separately in addition to code for primary procedure)	1.38	1.80	1.80	No
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; each additional vessel (List separately in addition to code for primary procedure)	1.00	1.44	1.44	No
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time	0.85	0.85	0.85	No
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	2.30	2.40	2.40	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	1.59	1.66	1.66	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes	0.55	0.57	0.57	No
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	0.23	0.24	0.24	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes	0.11	0.11	0.11	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	1.70	1.77	1.77	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes	0.60	0.63	0.63	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional	0.24	0.28	0.28	No
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection	0.17	0.17	0.17	No
97007	Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education	NEW	0.00	0.00	No
97008	Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period	NEW	0.00	0.00	No
97009	Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure)	NEW	0.00	0.00	No
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period	0.00	C	0.00	No
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period	0.00	0.00	0.00	No
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period	C	C	C	No
98979	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes	NEW	0.31	0.31	No
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 20 minutes	0.62	0.62	0.62	Yes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)	0.61	0.61	0.61	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
98984	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period	NEW	C	0.00	No
98985	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period	NEW	0.00	0.00	No
98986	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period	NEW	C	C	No
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	1.10	1.10	1.10	Yes
99445	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period	NEW	0.00	0.00	No
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period	0.00	0.00	0.00	No
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 20 minutes	0.61	0.61	0.61	Yes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)	0.61	0.61	0.61	No
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes	NEW	0.31	0.31	No
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	0.00	0.00	0.00	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	0.18	0.18	0.18	No
G0568	Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately in addition to the Advanced Primary Care Management code).	NEW	1.88	1.88	No
G0569	Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment (list separately in addition to Advanced Primary Care Management code).	NEW	2.05	2.05	No

HCPCS	Descriptor	CY 2025 Work RVU	Proposed CY 2026 Work RVU	Final CY 2026 Work RVU	CMS time refinement
G0570	Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team (list separately in addition to Advanced Primary Care Management code).	NEW	0.93	0.93	No
G0571	Intraoperative nerve(s) cryoablation for post-surgical pain relief	NEW	-	1.39	No

TABLE A-E13: CY 2026 DIRECT PE REFINEMENTS

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
37254	Revsc evasc ivt angio sf 1st	ED053	Professional PACS Workstation	NF		34	79	E18: Refined equipment time to conform to established policies for PACS Workstations	2.76
37256	Revsc evasc ivt angio cplx 1	ED053	Professional PACS Workstation	NF		34	99	E18: Refined equipment time to conform to established policies for PACS Workstations	3.98
37258	Revsc evasc ivt stent sf 1st	ED053	Professional PACS Workstation	NF		34	94	E18: Refined equipment time to conform to established policies for PACS Workstations	3.68
37260	Revsc evasc ivt st cplx 1st	ED053	Professional PACS Workstation	NF		34	136	E18: Refined equipment time to conform to established policies for PACS Workstations	6.25
37263	Revsc evasc fpvt angio sf 1	ED053	Professional PACS Workstation	NF		34	79	E18: Refined equipment time to conform to established policies for PACS Workstations	2.76

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
37265	Revsc evsc fpvt angio cplx 1	ED053	Professional PACS Workstation	NF		34	109	E18: Refined equipment time to conform to established policies for PACS Workstations	4.60
37267	Revsc evsc fpvt stent sf 1st	ED053	Professional PACS Workstation	NF		34	94	E18: Refined equipment time to conform to established policies for PACS Workstations	3.68
37269	Revsc evasc fpvt st cplx 1st	ED053	Professional PACS Workstation	NF		34	129	E18: Refined equipment time to conform to established policies for PACS Workstations	5.82
37271	Revsc evsc fpvt athrc sf 1st	ED053	Professional PACS Workstation	NF		34	109	E18: Refined equipment time to conform to established policies for PACS Workstations	4.60
37273	Revsc evsc fpvt athrc cplx 1	ED053	Professional PACS Workstation	NF		34	137	E18: Refined equipment time to conform to established policies for PACS Workstations	6.31

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
37275	Rvsc evsc fpvt st athrc sf 1	ED053	Professional PACS Workstation	NF		34	134	E18: Refined equipment time to conform to established policies for PACS Workstations	6.13
37277	Rvsc evsc fpvt st athr cpx 1	ED053	Professional PACS Workstation	NF		34	142	E18: Refined equipment time to conform to established policies for PACS Workstations	6.62
37280	Revsc evsc tpvt angio sf 1st	ED053	Professional PACS Workstation	NF		34	109	E18: Refined equipment time to conform to established policies for PACS Workstations	4.60
37282	Rvsc evsc tpvt angio cplx 1	ED053	Professional PACS Workstation	NF		34	119	E18: Refined equipment time to conform to established policies for PACS Workstations	5.21
37284	Revsc evasc tpvt st sf 1st	ED053	Professional PACS Workstation	NF		34	119	E18: Refined equipment time to conform to established policies for PACS Workstations	5.21

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
37286	Revsc evasc tpvt st cplx 1st	ED053	Professional PACS Workstation	NF		34	139	E18: Refined equipment time to conform to established policies for PACS Workstations	6.44
37288	Revsc evsc tpvt athrc sf 1st	ED053	Professional PACS Workstation	NF		34	139	E18: Refined equipment time to conform to established policies for PACS Workstations	6.44
37290	Revsc evsc tpvt athrc cplx 1	ED053	Professional PACS Workstation	NF		34	169	E18: Refined equipment time to conform to established policies for PACS Workstations	8.27
37292	Rvsc evsc tpvt st athrc sf 1	ED053	Professional PACS Workstation	NF		34	161	E18: Refined equipment time to conform to established policies for PACS Workstations	7.78
37294	Rvsc evsc tpvt st athr cpx 1	ED053	Professional PACS Workstation	NF		34	189	E18: Refined equipment time to conform to established policies for PACS Workstations	9.50

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
37296	Revsc evasc imvt angio sf 1	ED053	Professional PACS Workstation	NF		34	119	E18: Refined equipment time to conform to established policies for PACS Workstations	5.21
37298	Revsc evsc imvt angio cplx 1	ED053	Professional PACS Workstation	NF		34	139	E18: Refined equipment time to conform to established policies for PACS Workstations	6.44
47384	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.16
47384	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.02
47384	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.62
47384	Abltj ire liver 1+ tum perq	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	20	10	L8: Standard preservice	-5.40

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					(including test results)			clinical labor time for procedures with 0/10 day global periods	
52443	Cysto 1st trurl prst8 comis	EQ250	ultrasound unit, portable	NF		64	59	G1: See preamble text	-0.81
52443	Cysto 1st trurl prst8 comis	ES018	fiberscope, flexible, cystoscopy	NF		64	79	E4: Refined equipment time to conform to established policies for scopes	0.61
52443	Cysto 1st trurl prst8 comis	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		64	52	E4: Refined equipment time to conform to established policies for scopes	-3.21
52443	Cysto 1st trurl prst8 comis	L037D	RN/LPN/MTA	NF	Clean scope	40	30	L1: Refined time to standard for this clinical labor task	-5.40
52443	Cysto 1st trurl prst8 comis	L037D	RN/LPN/MTA	NF	Clean scope	0	10	G1: See preamble text	5.40
52648	Laser surgery of prostate	L037D	RN/LPN/MTA	F	Perform procedure/service---NOT directly related to physician work time	6	0	L1: Refined time to standard for this clinical labor task	-3.24
52648	Laser surgery of prostate	SL036	cup, biopsy-specimen sterile 4oz	NF		1	0	S5: Refined supply quantity to conform with other	-0.80

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								codes in the family	
55867	Laps surg prst8ect smpl stot	EF014	light, surgical	F		106	89	E7: Refined equipment time to conform to office visit duration	-0.05
55867	Laps surg prst8ect smpl stot	EF031	table, power	F		106	89	E7: Refined equipment time to conform to office visit duration	-0.27
55867	Laps surg prst8ect smpl stot	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	106	89	L9: Refined clinical labor to align with number of post-operative visits	-9.18
61626	Tcat perm occls/embol noncns	ED050	Technologist PACS workstation	NF		145	148	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
61626	Tcat perm occls/embol noncns	ED053	Professional PACS Workstation	NF		165	152	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.80
61626	Tcat perm occls/embol noncns	EF018	stretcher	NF		140	143	E1: Refined equipment time to conform to	0.06

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								established policies for non-highly technical equipment	
61626	Tcat perm occls/embol noncns	EF027	table, instrument, mobile	NF		140	143	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
61626	Tcat perm occls/embol noncns	EL011	room, angiography	NF		124	127	E2: Refined equipment time to conform to established policies for highly technical equipment	13.57
61626	Tcat perm occls/embol noncns	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		140	143	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
61626	Tcat perm occls/embol noncns	EQ032	IV infusion pump	NF		140	143	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02

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61626	Tcat perm occls/embol noncns	L037D	RN/LPN/MTA	NF	Coordinate post-procedure services	3	0	G1: See preamble text	-1.62
61626	Tcat perm occls/embol noncns	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	3	G1: See preamble text	1.62
61626	Tcat perm occls/embol noncns	SD089	guidewire, hydrophilic	NF		1	2	S8: Supply item replaces another item; see preamble SD172	27.42
61626	Tcat perm occls/embol noncns	SD172	guidewire, cerebral (Bentson)	NF		1	0	S7: Supply item replaced by another item; see preamble SD089	-48.27
77402	Radiation tx delivery lvl 1	ED035	video camera	NF		17	0	G1: See preamble text	-0.06
77402	Radiation tx delivery lvl 1	EQ139	intercom (incl. master, pt substation, power, wiring)	NF		17	0	G1: See preamble text	-0.06
77402	Radiation tx delivery lvl 1	ER039	laser targeting system (4 diodes)	NF		17	0	G1: See preamble text	-0.26
77402	Radiation tx delivery lvl 1	ER056	radiation treatment vault	NF		17	0	G1: See preamble text	-22.34
77402	Radiation tx delivery lvl 1	ER065	water chiller (radiation treatment)	NF		17	0	G1: See preamble text	-0.70
77402	Radiation tx delivery lvl 1	ER089	IMRT accelerator	NF		17	0	G1: See preamble text	-173.10
77402	Radiation tx delivery lvl 1	ER090	Computer system, record and verify, IMRT	NF		17	0	G1: See preamble text	-8.53

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77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-8.90
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-8.90
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0	G1: See preamble text	-0.89
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77402	Radiation tx delivery lvl 1	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	3	0	G1: See preamble text	-2.67
77402	Radiation tx delivery lvl 1	SB006	drape, non-sterile, sheet 40in x 60in	NF		1	0	G1: See preamble text	-0.13
77402	Radiation tx delivery lvl 1	SB022	gloves, non-sterile	NF		2	0	G1: See preamble text	-0.60
77402	Radiation tx delivery lvl 1	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77402	Radiation tx delivery lvl 1	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77402	Radiation tx delivery lvl 1	SM022	sanitizing cloth-wipe (surface,	NF		1	0	G1: See preamble text	-0.07

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			instruments, equipment)						
77407	Radiation tx delivery lvl 2	ED035	video camera	NF		22	0	G1: See preamble text	-0.07
77407	Radiation tx delivery lvl 2	EQ139	intercom (incl. master, pt substation, power, wiring)	NF		22	0	G1: See preamble text	-0.08
77407	Radiation tx delivery lvl 2	ER039	laser targeting system (4 diodes)	NF		22	0	G1: See preamble text	-0.33
77407	Radiation tx delivery lvl 2	ER056	radiation treatment vault	NF		22	0	G1: See preamble text	-28.91
77407	Radiation tx delivery lvl 2	ER065	water chiller (radiation treatment)	NF		22	0	G1: See preamble text	-0.91
77407	Radiation tx delivery lvl 2	ER089	IMRT accelerator	NF		22	0	G1: See preamble text	-224.01
77407	Radiation tx delivery lvl 2	ER090	Computer system, record and verify, IMRT	NF		22	0	G1: See preamble text	-11.04
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.	1	0	G1: See preamble text	-0.89
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0	G1: See preamble text	-0.89

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77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	15	0	G1: See preamble text	-13.35
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Review examination with interpreting MD/DO	2	0	G1: See preamble text	-1.78
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	3	0	G1: See preamble text	-2.67
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	2	0	G1: See preamble text	-1.78
77407	Radiation tx delivery lvl 2	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	15	0	G1: See preamble text	-13.35
77407	Radiation tx delivery lvl 2	SB006	drape, non-sterile, sheet 40in x 60in	NF		2	0	G1: See preamble text	-0.26
77407	Radiation tx delivery lvl 2	SB022	gloves, non-sterile	NF		2	0	G1: See preamble text	-0.60
77407	Radiation tx delivery lvl 2	SB026	gown, patient	NF		1	0	G1: See preamble text	-0.59
77407	Radiation tx delivery lvl 2	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77407	Radiation tx delivery lvl 2	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77407	Radiation tx delivery lvl 2	SM022	sanitizing cloth-wipe (surface,	NF		1	0	G1: See preamble text	-0.07

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			instruments, equipment)						
77412	Radiation tx delivery lvl 3	ED035	video camera	NF		31	0	G1: See preamble text	-0.10
77412	Radiation tx delivery lvl 3	EQ139	intercom (incl. master, pt substation, power, wiring)	NF		31	0	G1: See preamble text	-0.11
77412	Radiation tx delivery lvl 3	ER039	laser targeting system (4 diodes)	NF		31	0	G1: See preamble text	-0.47
77412	Radiation tx delivery lvl 3	ER056	radiation treatment vault	NF		31	0	G1: See preamble text	-40.73
77412	Radiation tx delivery lvl 3	ER065	water chiller (radiation treatment)	NF		31	0	G1: See preamble text	-1.28
77412	Radiation tx delivery lvl 3	ER089	IMRT accelerator	NF		31	0	G1: See preamble text	-315.66
77412	Radiation tx delivery lvl 3	ER090	Computer system, record and verify, IMRT	NF		31	0	G1: See preamble text	-15.56
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0	G1: See preamble text	-0.89
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Review examination with interpreting MD/DO	2	0	G1: See preamble text	-1.78
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	3	0	G1: See preamble text	-2.67

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77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	24	0	G1: See preamble text	-21.36
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	2	0	G1: See preamble text	-1.78
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.	1	0	G1: See preamble text	-0.89
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77412	Radiation tx delivery lvl 3	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	24	0	G1: See preamble text	-21.36
77412	Radiation tx delivery lvl 3	L152A	Medical Physicist	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-10.70
77412	Radiation tx delivery lvl 3	SB006	drape, non-sterile, sheet 40in x 60in	NF		2	0	G1: See preamble text	-0.26
77412	Radiation tx delivery lvl 3	SB022	gloves, non-sterile	NF		2	0	G1: See preamble text	-0.60
77412	Radiation tx delivery lvl 3	SB026	gown, patient	NF		1	0	G1: See preamble text	-0.59
77412	Radiation tx delivery lvl 3	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47

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77412	Radiation tx delivery lvl 3	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77412	Radiation tx delivery lvl 3	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.07
77436	Surf radj ther tx planning	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional--- directly related to physician work time (100% of physician intraservice time)	2	0	G1: See preamble text	-1.08
77436	Surf radj ther tx planning	SB026	gown, patient	NF		1	0	G1: See preamble text	-0.59
77437	Surf radj ther supfc<=150kv	EF031	table, power	NF		17	0	G1: See preamble text	-0.27
77437	Surf radj ther supfc<=150kv	EQ168	light, exam	NF		17	0	G1: See preamble text	-0.06
77437	Surf radj ther supfc<=150kv	ER045	Superficial radiation therapy system	NF		17	0	G1: See preamble text	-25.44
77437	Surf radj ther supfc<=150kv	ER120	Lead Blocking Shield Kit	NF		17	0	G1: See preamble text	-0.15
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.54
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-1.62
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	2	0	G1: See preamble text	-1.08

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77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	2	0	G1: See preamble text	-1.08
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	1	0	G1: See preamble text	-0.54
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-1.62
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G1: See preamble text	-1.08
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	0	G1: See preamble text	-1.62
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	2	0	G1: See preamble text	-1.08
77437	Surf radj ther supfc<=150kv	L037D	RN/LPN/MTA	NF	Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)	2	0	G1: See preamble text	-1.08
77437	Surf radj ther supfc<=150kv	SB023	gloves, non-sterile, nitrile	NF		2	0	G1: See preamble text	-2.12
77437	Surf radj ther supfc<=150kv	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77437	Surf radj ther supfc<=150kv	SG035	dressing, 3in x 4in (Telfa, Release)	NF		1	0	G1: See preamble text	-0.05
77437	Surf radj ther supfc<=150kv	SG079	tape, surgical paper 1in (Micropore)	NF		8	0	G1: See preamble text	-0.08

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77437	Surf radj ther supfc<=150kv	SJ038	petroleum jelly	NF		1	0	G1: See preamble text	-0.37
77437	Surf radj ther supfc<=150kv	SJ053	swab-pad, alcohol	NF		1	0	G1: See preamble text	-0.04
77437	Surf radj ther supfc<=150kv	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77437	Surf radj ther supfc<=150kv	SM013	disinfectant, surface (Envirocide, Sanizide)	NF		1	0	G1: See preamble text	-0.18
77438	Surf rad thr orthvlt>150-500	EF023	table, exam	NF		15	0	G1: See preamble text	-0.16
77438	Surf rad thr orthvlt>150-500	ER128	Orthovoltage Treatment Delivery System	NF		15	0	G1: See preamble text	-22.87
77438	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Clean room/equipment by clinical staff	3	0	G1: See preamble text	-2.67
77438	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-4.45
77438	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-4.45
77438	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	2	0	G1: See preamble text	-1.78
77438	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Prepare room, equipment and supplies	2	0	G1: See preamble text	-1.78

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77438	Surf rad thr orthvlt>150-500	L050C	Radiation Therapist	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G1: See preamble text	-2.67
77438	Surf rad thr orthvlt>150-500	SB006	drape, non-sterile, sheet 40in x 60in	NF		2	0	G1: See preamble text	-0.26
77438	Surf rad thr orthvlt>150-500	SB023	gloves, non-sterile, nitrile	NF		2	0	G1: See preamble text	-2.12
77438	Surf rad thr orthvlt>150-500	SB037	pillow case	NF		1	0	G1: See preamble text	-0.47
77438	Surf rad thr orthvlt>150-500	SK075	skin marking pen, sterile (Skin Skribe)	NF		1	0	G1: See preamble text	-1.62
77438	Surf rad thr orthvlt>150-500	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.07
91124	Rct snsatn tone&cmplianc std	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	30	10	G1: See preamble text	-10.80
91124	Rct snsatn tone&cmplianc std	SM015	enzymatic detergent	NF		120	8	S6: Refined supply quantity to what is typical for the procedure	-24.64
91125	Anrct mano rct snsatn&balo	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	30	10	G1: See preamble text	-10.80
91125	Anrct mano rct snsatn&balo	SM015	enzymatic detergent	NF		120	8	S6: Refined supply quantity to what is typical for the procedure	-24.64

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97007	Mchnl sclp cool meas fitg	L056A	RN/OCN	NF	Perform procedure/service---NOT directly related to physician work time	5	27	G1: See preamble text	17.82
97008	Mchnl sclp cool prep plmt	EF009	chair, medical recliner	NF		0	30	G1: See preamble text	0.18
97009	Mchnl sclp cool after chemo	EF009	chair, medical recliner	NF		0	30	G1: See preamble text	0.18
98975	Rem ther mntr 1st setup&edu	L039B	Physical Therapy Assistant	NF	Conduct patient communications	0	10	G1: See preamble text	6.10
98975	Rem ther mntr 1st setup&edu	L039B	Physical Therapy Assistant	NF	Prepare room, equipment and supplies	2	0	G1: See preamble text	-1.22
98975	Rem ther mntr 1st setup&edu	SK057	paper, laser printing (each sheet)	NF		1	0	G1: See preamble text	-0.02
98979	Rtm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	5	G1: See preamble text	2.70
98979	Rtm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	15	G1: See preamble text	8.10
98979	Rtm tx mgmt 1st 10 min	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	5	0	G1: See preamble text	-3.05
98979	Rtm tx mgmt 1st 10 min	L039B	Physical Therapy Assistant	NF	Conduct patient communications	10	0	G1: See preamble text	-6.10
98980	Rtm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	G1: See preamble text	5.40

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98980	Rtm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	30	G1: See preamble text	16.20
98980	Rtm tx mgmt 1st 20 min	L039B	Physical Therapy Assistant	NF	Conduct patient communications	15	0	G1: See preamble text	-9.15
98980	Rtm tx mgmt 1st 20 min	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-6.10
98981	Rtm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	0	10	G1: See preamble text	5.40
98981	Rtm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	G1: See preamble text	5.40
98981	Rtm tx mgmt ea addl 20 min	L039B	Physical Therapy Assistant	NF	Perform procedure/service---NOT directly related to physician work time	10	0	G1: See preamble text	-6.10
98981	Rtm tx mgmt ea addl 20 min	L039B	Physical Therapy Assistant	NF	Conduct patient communications	5	0	G1: See preamble text	-3.05
99445	Rem mntr physiol param 2-15	EQ392	heart failure patient physiologic monitoring equipment package	NF		20160	0	G1: See preamble text	-22.80
99445	Rem mntr physiol param 2-15	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	11	0	G1: See preamble text	-5.94
99445	Rem mntr physiol param 2-15	SD385	digital remote physicologic monitoring device app	NF		1	0	G1: See preamble text	-6.62

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99454	Rem mntr physiol param 16-30	EQ392	heart failure patient physiologic monitoring equipment package	NF		43200	0	G1: See preamble text	-48.85
99454	Rem mntr physiol param 16-30	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	11	0	G1: See preamble text	-5.94
99454	Rem mntr physiol param 16-30	SD385	digital remote physicologic monitoring device app	NF		1	0	G1: See preamble text	-6.62
99457	Rpm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	12	30	G1: See preamble text	9.72
99457	Rpm tx mgmt 1st 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	8	10	G1: See preamble text	1.08
99458	Rpm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	12	10	G1: See preamble text	-1.08
99458	Rpm tx mgmt ea addl 20 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	7	10	G1: See preamble text	1.62
99470	Rpm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Conduct patient communications	6	15	G1: See preamble text	4.86
99470	Rpm tx mgmt 1st 10 min	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	3	5	G1: See preamble text	1.08

TABLE A-E14: CY 2026 DIRECT PE REFINEMENTS – EQUIPMENT REFINEMENTS CONFORMING TO CHANGES IN CLINICAL LABOR TIME

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
52648	Laser surgery of prostate	EF031	table, power	F		95	89	E15: Refined equipment time to conform to changes in clinical labor time	-0.09

TABLE A-E15: CY 2026 INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
0446T, 0448T	implantable interstitial glucose sensor	SD334	$3,000.00	$6,000.00	100%	-	620
0446T, 99445, 99454	patient physicologic monitoring equipment package	EQ392	$1,000.00	$1,000.00	0%	0	2,320,898
36514	cell separator system	EQ084	$81,656.40	$93,705.58	15%	46	218
37254, 37256, 37258, 37260, 37263, 37265, 37267, 37269, 37271, 37273, 37275, 37277, 37280, 37282, 37284, 37286, 37288, 37290, 37292, 37294, 37296, 37298 + 74 other codes	guidewire, hydrophilic	SD089	$20.56	$27.42	33%	3	-
37254, 37256, 37258, 37260, 37263, 37265, 37267, 37269, 37271, 37273, 37275, 37277, 37280, 37282, 37284, 37286, 37288, 37290, 37292, 37294, 37296, 37298 + 40 other codes	catheter, (Glide)	SD147	$48.95	$50.65	3%	3	-
37260, 37261, 37268, 37269, 37270, 37276, 37277, 37278 + 2 other codes	covered stent (VIABAHN)	SD254	$3,129.00	$3,931.17	26%	5	5,772
37260, 37269, 37273, 37277, 37282, 37286, 37290, 37294	Reentry device (Frontier, Outback, Pioneer)	SD255	$2,343.12	$3,100.00	32%	2	28,041
37271, 37273, 37275, 37277, 37288, 37290,	atherectomy device	SD253	$3,048.33	$3,447.50	13%	2	63,494

37292, 37294							
53854	kit, Rezum delivery device	SA128	$1,220.00	$3,090.00	153%	6	2,648
55874	Biodegradable Material Kit - PeriProstatic	SA126	$2,965.00	$4,036.22	36%	9	7,466
77402, 77407, 77412	Radiation Treatment Delivery Linear Accelerator	ER089	$3,000,966.47	$3,999,493.00	33%	1	1,502,416
77402, 77407, 77412	water chiller (radiation treatment)	ER065	$9,847.33	$15,309.00	55%	1	1,502,416
77437	Superficial radiation therapy system	ER045	$204,999.67	$395,000.00	93%	1	452,289
88182, 88184, 88185	flow cytometer	EP014	$205,774.80	$211,250.00	3%	1	2,133,243
88182, 88184, 88185	Isoton II diluent	SL084	$0.0020	$0.0035	75%	3	2,133,243
88184	calibration beads (each test)	SL021	$11.46	$13.09	14%	3	92,800
88184, 88185	lysing reagent (FACS)	SL089	$5.532	$6.009	9%	3	2,132,513
88344	34 Beta E12	SL496	$5.38	$8.34	55%	3	107,784
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	$18.01	$20.91	16%	6	371,033
91040, 91124	barostat system, with hardware & software	EQ070	$23,625.00	$39,275.00	66%	1	315
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$292.50	$315.00	8%	34	672,717
95144, 95165	antigen, multi (pollen, mite, mold, cat)	SH007	$8.96	$13.00	45%	69	5,917,413
G0138	Opfolda (65 mg capsule)	SH111	$33.00	$33.53	2%	1	93
G2082	Esketamine (56 mg vial)	SH109	$772.41	$834.20	8%	1	4,344
G2083	Esketamine (84 mg vial)	SH110	$1,158.62	$1,251.31	8%	1	32,155
111 codes	pack, basic injection	SA041	$10.45	$12.73	22%	-	-
306 codes	pack, cleaning and disinfecting, endoscope	SA042	$22.40	$25.36	13%	-	-
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%	-	-
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%	-	-
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$4.01	-20%	-	-

168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$2.26	-17%	-	-
239 codes	pack, pelvic exam	SA051	$20.16	$14.38	-29%	-	-
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$6.50	35%	-	-
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$7.49	37%	-	-
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$6.53	41%	-	-
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$10.93	50%	-	-
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$9.48	53%	-	-
38 codes	pack, urology cystoscopy visit	SA058	$94.68	$75.67	-20%	-	-
120 codes	pack, drapes, ortho, large	SA080	$37.30	$33.33	-11%	-	-
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%	-	-
145 codes	pack, ophthalmology visit (w-dilation)	SA082	$3.52	$3.12	-11%	-	-
119 codes	pack, protective, ortho, large	SA083	$10.86	$12.16	12%	-	-
27 codes	pack, protective, ortho, small	SA084	$5.99	$6.71	12%	-	-

TABLE A-E16: CY 2026 NEW INVOICES

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
37254, 37256, 37258, 37260, 37263, 37265, 37267, 37269, 37271, 37273, 37275, 37277, 37280, 37282, 37284, 37286, 37288, 37290, 37292, 37294, 37296, 37298	pack, angiography	SA142	62.26	1	81,902
37262	Iliac IVL Catheter	SD380	3,450.00	3	374
37262, 37279	IVL generator	EQ413	15,000.00	1	1,779
37263, 37264, 37265, 37266, 37267, 37271, 37272, 37273, 37274, 37275	Drug coated balloon	SD382	2,343.33	3	41,255
37267, 37275	Drug eluting stent	SD383	1,900.00	1	9,110
37271, 37273, 37275, 37277, 37288, 37290, 37292, 37294	Embolic protection for atherectomy	SD384	2,862.00	1	63,494
37279	FemPop IVL Catheter	SD381	4,700.00	3	1,405
37284, 37285, 37286, 37287, 37292, 37293, 37294, 37295	drug eluting stent, tibial	SD379	2,750.00	4	2,643
52443	Optilume BPH Prostatic Dilation Kit	SA138	5,900.00	10	1

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
55705, 55707, 55708, 55709, 55710, 55711, 55712	Disposable Prostate Core Biopsy Needle	SC110	43.85	1	58,849
55707, 55708, 55711	Transrectal Ultrasound Biopsy Guide	SD376	17.31	1	45,735
55708, 55710, 55711, 55712, 55715	UroNav system	ER127	181,998.45	1	21,540
55709, 55710, 55712	Transperineal Ultrasound Biopsy Guide	SD373	237.00	1	11,287
55713, 55714	Transrectal MRI-compatible -150mm fully automatic biopsy gun	SD374	180.00	1	1,213
55713, 55714	Transrectal MRI-compatible needle guide	SD375	150.00	1	1,213
64567	IB-Stim device kit	SA139	1,195.00	4	0
64567	Adhesive dot 10mm	SK135	0.19	1	0
64728	Kit, UltraguideCTR	SA140	1,099.00	3	75
77438	Orthovoltage Treatment Delivery System	ER128	498,961.00	1	11,912
91125	Anorectal expulsion balloon	SD377	35.25	2	13,451
91125	Sheath, catheter	SD378	39.00	2	13,451
92288	Dark Adaptometer, Second Generation	ER126	61,758.00	1	0
97007	Scalp Cooling Cap/Kit	SA141	1,800.00	6	2
99445, 99454	digital remote physicologic monitoring device app	SD385	6.62	1	2,320,580
No codes	Digital mental health device (insomnia)	SD386	800.00	4	-

TABLE A-E17: CY 2026 NO PE REFINEMENTS

HCPCS	Description
0596T	Temp fml iu vlv-pmp 1st insj
0597T	Temp fml iu valve-pmp rplcmt
27458	Osteot femur imed lngth dev
27465	Shortening of thigh bone
27466	Lengthening of thigh bone
27713	Osteot tibia imed lngth dev
27715	Revision of lower leg
28750	Fusion of big toe joint
28755	Fusion of big toe joint
33340	Perq clsr tcat l atr apndge
33880	Evasc rpr ta ndgft cov lsa
33881	Evasc rpr ta ndgft xcov lsa
33882	Evasc rpr ta dplmt mltpc sys
33883	Delayed plmt prox xtn prosth
33886	Delayed plmt dstl xtn prosth
35602	Bpg crtd-clat crtd
37255	Revsc evasc ivt angio sf ea
37257	Revsc evsc ivt angio cplx ea

HCPCS	Description
37259	Revsc evasc ivt stent sf ea
37261	Revsc evasc ivt st cplx ea
37262	Iv lithotrp ivt w/in sm art
37264	Revsc evasc fpvt angio sf ea
37266	Rvsc evsc fpvt angio cplx ea
37268	Revsc evasc fpvt stent sf ea
37270	Revsc evasc fpvt st cplx ea
37272	Revsc evsc fpvt athrc sf ea
37274	Rvsc evsc fpvt athrc cplx ea
37276	Rvsc evsc fpvt st athr sf ea
37278	Rvsc evsc fpvt st ath cpx ea
37279	Iv lithotrp fpvt w/in sm art
37281	Revsc evsc tpvt angio sf ea
37283	Rvsc evsc tpvt angio cplx ea
37285	Revsc evasc tpvt st sf ea
37287	Revsc evasc tpvt st cplx ea
37289	Revsc evsc tpvt athrc sf ea
37291	Revsc evsc tpvt athr cplx ea
37293	Rvsc evsc tpvt st athr sf ea
37295	Rvsc evsc tpvt st ath cpx ea
37297	Revsc evasc imvt angio sf ea
37299	Revsc evsc imvt angio cpx ea
43889	Gstr rstcv px trnsorl esg
52500	Revision of bladder neck
52597	Trurl rbtc wtrjt rescj prst8
52601	Prostatectomy (turp)
52630	Remove prostate regrowth
52649	Prostate laser enucleation
55705	Bx prst8 any approach nonimg
55706	Prostate saturation sampling
55707	Bx prst8 trct us guided
55708	Bx prst8 trct us w/mri fus 1
55709	Bx prst8 tprnl us guided
55710	Bx prst8 tprn us w/mri fus 1
55711	Bx prst8 trct mri-us 1st
55712	Bx prst8 tprnl mri-us 1st
55713	Bx prst8 in-bore ct/mri bx 1
55714	Bx prst8 in-bore ct/mri 1
55715	Bx prst8 ea add mri-us/ct/mr
55840	Extensive prostate surgery
55842	Extensive prostate surgery
55845	Extensive prostate surgery
55866	Laps surg prst8ect rpbic rad
55868	Lap srg prst8ct lymph nod bx
55869	Lap srg prst8ct bi pl lmphad
55877	Abltj ire prst8 1+ tum perq
61624	Tcat perm occls/embolj cns
62330	Dcmprn prq rmv lig flv 1lmbr
62331	Dcmprn prq rmv lig flv addl
64567	Perq elec nrv field stimj cn
64654	1st opn implt bat modulj sys
64655	Revj/rplcmt bat mod sys lead
64656	Revj/rplcmt bat mod sys pg
64657	Rmvl bat modulj sys tot sys
64658	Rmvl bat modul sys lead only
64659	Rmvl bat modulj sys pg only

HCPCS	Description
64728	Dcmprn median nrv carpl tunl
70471	Cta h&n c+ w/noncontrast img
70472	Ct cere prfu alys c+w/ct/cta
70473	Ct cere prfu aly c+wo ct/cta
70496	Ct angiography head
70498	Ct angiography neck
75577	Quan&char c athrosclrtc plaq
75894	X-rays transcath therapy
75898	Follow-up angiography
76872	Us transrectal
90480	Admn sarscov2 vac 1/only cmp
90482	Imm cnsl not admn sm 3<10
90483	Imm cnsl not admn sm>10<20
90484	Imm cnsl not admn sm>20
92284	Dx dark adaptation exam i&r
92288	Scr dark adaptation meas i&r
93145	Interrog crtd sins bat ip wo
93146	Interrog crtd sins bat ip w/
96380	Admn rsv monoc antb im cnsl
96381	Admn rsv monoc antb im njx
99091	Collj & interpj data ea 30 d
99453	Rem mntr physiol param setup
99473	Self-meas bp pt educaj/train
99474	Self-meas bp 2 readg bid 30d

F. Evaluation and Management (E/M) Visits

1. Evaluation and Management (E/M) Visit Complexity Add-on

In the CY 2024 PFS final rule (88 FR 78970 through 78982), we finalized separate payment for the office/outpatient evaluation and management (O/O E/M) visit complexity add-on code, HCPCS code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*).

In the CY 2024 PFS final rule, we noted that the O/O E/M visit complexity add-on code "reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M visit services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high-risk disease) and to address the majority of a patient's health care needs with consistency and continuity over longer periods of time." (88 FR 78970 through 78971). We explained in the CY 2024 PFS final rule that it is the relationship between the patient and the practitioner that is the determining factor for when the add-on code should be billed. The add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship. The first part of the code descriptor, the "continuing focal point for all needed health care services," describes a relationship between the patient and the practitioner when the practitioner is the continuing focal point for all health care services that the patient needs. The second part of the add-on code also describes a relationship involving medical services that are part of ongoing care related to a patient's single, serious condition or a complex condition. There is previously unrecognized but important cognitive effort of utilizing the longitudinal relationship in making a diagnosis, developing a treatment plan, and weighing the factors that affect a longitudinal doctor-patient relationship. The practitioner must decide what course of action and choice of words in the visit itself would lead to the best health outcome in the single visit while simultaneously building up an effective, trusting longitudinal relationship with the patient. Weighing these various factors, even for a seemingly simple condition, makes the entire visit inherently complex, which is what this add-on code is intended to capture (88 FR

78973 through 78974).

Interested parties have recommended that CMS either establish separate payment for an evaluation and management inherent complexity add-on code specific to home-based visits or expand use of the O/O E/M visit complexity add-on code HCPCS code G2211 to be reported alongside home and residence E/M visits furnished to beneficiaries in nursing facilities, assisted living facilities, and the beneficiary's home. Interested parties have explained that home-based primary care practices provide access to primary care services for patients who otherwise would not be able to leave the house to see a primary care practitioner, and include the development of longitudinal, "high-touch" relationships with their patients.

In the CY 2024 PFS final rule (88 FR 78818, 78971), we stated that the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with separate payment for HCPCS code G2211 (85 FR 84569, 87 FR 69588), and that we finalized work RVUs for the nursing facility E/M visit codes (87 FR 69604 through 69606) and the home or residence services code family (87 FR 69608 and 69609) subsequently in the CY 2023 PFS final rule. We stated that we may nevertheless consider in future rulemaking whether home or residence evaluation and management services bear unrecognized resource costs and whether HCPCS code G2211 should be applicable to home or residence E/M visits. We have noted that the application of the add-on code is not based on the characteristics of particular patients (even though the rationale for valuing the code is based on recognizing the typical complexity of patient needs), but rather the relationship between the patient and the practitioner (88 FR 78973). In part, HCPCS code G2211 recognizes the resource costs involved in building trust in a long-term practitioner-patient relationship that are not reflected in the valuation of the O/O E/M code set. The same appears to be true about the home and residence evaluation and management code set. Building trust as part of a longitudinal practitioner-patient relationship may be particularly significant in the context of home and residence E/M visits. Typically, home visits occur at least monthly and people with serious illness may receive weekly visits. These visits involve developing and following through on a longitudinal care plan with proactive contacts regarding all of a person's health care needs. The follow-through based on a trusting practitioner/patient relationship is critical to keeping patients stable and preventing exacerbations. For these reasons, we believed it was appropriate to extend the

application of HCPCS code G2211 to home and residence E/M visits in the CY 2026 MPFS. Therefore, we proposed to allow HCPCS code G2211 to be billed as an add-on code with the home or residence evaluation and management visits code family (CPT codes 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350). The HCPCS code G2211 refined descriptor would read as follows, "*(Visit complexity inherent to evaluation and management* associated with *medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add*-on code, *list separately in addition to home or residence or* office/outpatient *evaluation and management* service*, new* or *established))".*

The following is a summary of the comments we received and our responses.

Comment: Many comments supported our proposed refinement to HCPCS code G2211 to make this add-on code payable when reported with home residence E/M visits. Many commenters recommended that we make the add-on code applicable to other or all types of E/M visits and to home visits reported by community health centers and rural health clinics. A commenter also suggested making the transitional care management (TCM) services codes new base codes for HCPCS code G2211. Another handful of commenters opposed our proposal.

Many commenters, including those who supported our proposal, expressed concerns over the CY 2024 PFS final rule estimate of the utilization of HCPCS code G2211 resulting in a negative impact to the conversion factor for that year. Some commenters expressed concern that our proposal to make the home residence E/M visit codes base codes for the HCPCS code G2211 add-on code would trigger larger budget neutrality adjustments going forward. Many commenters recommended a prospective budget neutrality adjustment to the 2026 Conversion Factor (CF) to account for the estimated utilization that was not realized in CY 2024.

Response: We appreciate the commenters for their feedback that this policy will support ongoing, longitudinal care relationships with primary care providers for populations with complex co-morbidities. We also acknowledge receipt of recommendations beyond the scope of this proposal, requesting additional service codes be designated base codes to which the HCPCS code G2211 add-on code would apply, requesting that we revisit the modifier 25 payment policy restriction on certain services or

procedures reported on the same day by the same practitioner, and recommendations to provide patient education about applicability of patient co-pays.

Regarding the concerns about utilization estimates, we acknowledge that the CY 2024 utilization estimate exceeded actual reporting of HCPCS code G2211 in CY 2024. We remind commenters that we do not make retrospective budget neutrality adjustments and would not compare actual claims reported for new coding against the utilization estimates made in the PFS final rule for the year in which such reporting began. As noted in the CY 2024 PFS final rule (88 FR 78975), CMS makes budget neutrality calculations on a prospective annual basis and uses claims data for the services as they become available in subsequent years, to inform budget neutrality adjustments. Utilization is variable and for new coding, estimates sometimes do not anticipate the volume of reporting that is actually realized.

We continue to anticipate that utilization of the inherent complexity add-on code will continue to increase over time, consistent with utilization patterns for other new services, and we remain interested and appreciative of feedback regarding how to encourage its appropriate use.

After reviewing all the comments, we are finalizing as proposed, to allow HCPCS code G2211 to be billed as an add-on code with the home or residence E/M visits code family (CPT codes 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350). We are also finalizing refinement of the HCPCS code G2211 code descriptor to read as follows, "*(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to home or residence or office/outpatient evaluation and management service, new or established))*".

Lastly, we note that the add-on code for inherent complexity intends to address the lack of distinction between E/M codes used to describe visits that involve a longitudinal relationship between the practitioner and patient compared to visits that do not. Similar to the discussion in section II.B. of this final rule regarding site of service payment differentials, we look forward to ongoing feedback on improved approaches to recognize those differences more holistically without use of an add-on code and recognize that there continues to be an imbalance in payment for E/M visits that are part of ongoing care.

At the same time, we recognize we would need to address any potential changes through future notice and comment rulemaking.

G. Enhanced Care Management

1. Integrating Behavioral Health into Advanced Primary Care Management (APCM)

In the CY 2025 PFS final rule (89 FR 97859 through 97902), we finalized separate coding and payment for Advanced Primary Care Management (APCM) services (HCPCS codes G0556, G0557, and G0558).

TABLE A-G1: 25 APCM CODES

Code	G0556	G0557	G0558
Population	For beneficiaries with one chronic condition or fewer	For beneficiaries with multiple (two more more) chronic conditions	For beneficiaries who are a Qualified Medicare Beneficiaries with multiple (two or more) chronic conditions
Long Descriptor	*Advanced primary care management services for a patient with one chronic condition [expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline], or fewer, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:* *● Consent;* *++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.* *++ Document in patient's medical record that consent was obtained.* *● Initiation during a qualifying visit for new patients or patients not seen within 3 years;* *● Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers*	*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:* *● Consent;* *++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.* *++ Document in patient's medical record that consent was obtained.* *● Initiation during a qualifying visit for new patients or patients not seen within 3 years;* *● Provide 24/7 access for urgent needs to care team/practitioner, including*	*Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:* *● Consent;* *++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.* *++ Document in patient's medical record that consent was obtained.* *● Initiation during a qualifying visit for new patients or patients not seen within 3 years;* *Provide 24/7 access for urgent needs to care*

Code	G0556	G0557	G0558
	with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week; *● Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;* *● Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;* *● Overall comprehensive care management;* *++ Systematic needs assessment (medical and psychosocial).* *++ System-based approaches to ensure receipt of preventive services.* *++ Medication reconciliation, management and oversight of self-management.* *● Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan with typical care plan elements when clinically relevant;* *++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;* *● Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;* *++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.* *++ Ensure timely follow-up communication (direct contact, telephone, electronic)*	*providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;* *● Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;* *● Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;* *● Overall comprehensive care management;* *++ Systematic needs assessment (medical and psychosocial).* *++ System-based approaches to ensure receipt of preventive services.* *++ Medication reconciliation, management and oversight of self-management.* *● Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;* *++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;* *● Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;* *++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.* *++ Ensure timely follow-up communication (direct*	*team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;* *● Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;* *●Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;* *● Overall comprehensive care management;* *++ Systematic needs assessment (medical and psychosocial).* *++ System-based approaches to ensure receipt of preventive services.* *++ Medication reconciliation, management and oversight of self-management.* *● Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;* *++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;* *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;* *++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.*

Code	G0556	G0557	G0558
	with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated. ● *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;* ● *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;* ++ *Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).* ● *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*	*contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.* ● *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;* ● *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;* ++ *Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).* ● *Analyze patient population data to identify gaps in care*	++ *Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.* ● *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;* ● *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;* ++ *Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).*

Code	G0556	G0557	G0558
	● *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;* ● *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology*).	*and offer additional interventions, as appropriate;* ● *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;* ● *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).	● *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;* ● *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;* ● *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology*)

In the CY 2017 PFS final rule (81 FR 80230), we began making separate payment to practitioners who provide behavioral health integration (BHI) services to patients using the Psychiatric Collaborative Care Model (CoCM) (a specific model of care provided by a primary care team consisting of a primary care provider and a health care manager who works in collaboration with a psychiatric consultant) using HCPCS codes G0502, G0503, and G0504.

In the CY 2018 PFS final rule (82 FR 53077 through 53078), these codes were replaced by CPT codes 99492 (Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies), 99493 (Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate

documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment), and 99494 (Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure)), respectively.

In the CY 2017 PFS final rule (81 FR 80230), we also began making separate payment to practitioners who provide general BHI services to patients, using HCPCS code G0507. BHI is a term that refers broadly to collaborative care that integrates behavioral health services with primary care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. In the CY 2018 PFS final rule (82 FR 53077 through 53078), HCPCS code G0507 was replaced by CPT code 99484.

CPT code 99484 is for care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team.

Patients with chronic health conditions are "more likely to have related behavioral health concerns and find it easier to improve chronic conditions when these concerns are also addressed."[76] Integrating behavioral health with primary care has been shown to improve outcomes like reduced depression severity, and enhancing patient's experience of care.[77] In the CY 2025 PFS final rule (89 FR 97897), we summarized comments that we had received on our APCM services proposals discussing the importance of behavioral health on overall health and urging us to consider including behavioral health in future rulemaking as it relates to advanced primary care, citing the growing need for fully integrated physical and behavioral health. In our response, we agreed with commenters that behavioral health integration services are complementary to APCM services and that behavioral health is important in the context of overall health. We stated that we will take comments recommending strategies for further integration into consideration for future rulemaking. We further stated that we continue to be interested in the use of behavioral health integration services as they relate to advanced primary care and welcome input from interested parties, including how evolving changes in practice may warrant reconsideration of payment and coding policies.

We believe that the physicians and practitioners who furnish APCM services should be able to provide BHI services and CoCM without needing to document their time spent performing the service because this would help facilitate a more holistic, team-based approach to care coordination and reduce burden. Otherwise, the practice would need to develop a time documentation system for BHI and CoCM, but not APCM. Functionally, we also believe that many practices that develop the interdisciplinary teams to provide advanced primary care are also the ones most likely ready to furnish BHI and CoCM services, so alignment in billing requirements would streamline processes. Therefore, for CY 2026, we proposed to create optional add-on codes for APCM services that would facilitate providing complementary BHI services by removing the time-based requirements of the existing BHI and CoCM codes. We believe that removing the time-based requirements will reduce burden on practitioners by reducing the documentation requirements for billing. By reducing the documentation requirements, we also believe primary care

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[76] https://integrationacademy.ahrq.gov/about/integrated-behavioral-health#:~:text=Integrated%20behavioral%20health%20offers%20many,these%20concerns%20are%20also%20addressed.

[77] Balasubramanian, Bijal, Deborah Cohen, Katelyn Jetelina, Miriam Dickinson, Melinda Davis, Rose Gunn, Kris Gowen, Frank DeGruy 3rd, Benjamin Miller, Larry Green. "Outcomes of Integrated Behavioral Health with Primary Care." J Am Board Fam Med. 2017 Mar-Apr;30(2):130-139.doi: 10.3122/jabfm.2017.02.160234.

practitioners may be more likely to offer and furnish BHI and CoCM services, which would improve access to BHI and CoCM for primary care patients. These proposed optional add-on codes for APCM services would be considered a ''designated care management service'' at § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner. In the CY 2024 PFS final rule (88 FR 78939), we summarized comments received for Principal Illness Navigation services that discussed that patients with severe mental illness and substance use disorders may only see behavioral health practitioners regularly, which we believe makes the integration of behavioral health and primary care important for this population to improve access. We are opting to not create an add-on code for CPT code 99494 as this code is for an additional 30 minutes of initial or subsequent psychiatric collaborative care management in a calendar month, and the APCM codes, and proposed add-on codes do not require the counting of minutes to bill.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported that these proposed optional add-on codes for APCM services would be considered a ''designated care management service'' at § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

Response: We appreciate the commenters for their supportive comments.

2. Behavioral Health Integration Add-On Codes for APCM (HCPCS codes G0568, G0569, G0570)

We proposed the establishment of three new G-codes to be billed as add-on services when the APCM base code (HCPCS codes G0556, G0557, and G0558) is reported by the same practitioner in the same month. HCPCS code G0568, an add-on code based on CPT code 99492, HCPCS code G0569, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and HCPCS code G0570, an add-on code for general behavioral health integration services based on CPT code 99484. We did not propose to create an add-on code for CPT code 99494, as that code describes additional time, and these codes do not require the counting of minutes.

Our proposed code descriptors are listed below.

HCPCS code G0568: Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and

directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately in addition to the Advanced Primary Care Management code).

HCPCS code G0569: Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment (list separately in addition to Advanced Primary Care Management code).

HCPCS code G0570: Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and

continuity of care with a designated member of the care team (list separately in addition to Advanced Primary Care Management code).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to create three new G-codes to be billed as add-on services when the APCM base code (HCPCS codes G0556, G0557, and G0558) is reported by the same practitioner in the same month. They stated that this change will encourage primary care practices to provide integrated mental health care, including BHI and CoCM services, and improve Medicare beneficiaries' access to whole person, team-based care.

Response: We appreciate the commenters for their supportive comments.

Comment: Several commenters expressed support for the fact that these codes do not require the counting of minutes. The commenters stated that counting minutes is administratively burdensome and takes away time that practitioners would otherwise spend on patient care. However, a few commenters stated that the counting and documentation of minutes of service provided is necessary to ensure the appropriate services are delivered to beneficiaries and were concerned that without this requirement beneficiaries would not receive the care they need.

Response: We appreciate the commenters for their thoughtful comments. While we proposed not to require the counting of minutes for these add-on codes, we would expect that the care delivered to Medicare beneficiaries would be appropriately documented in the medical record, regardless of whether the counting of minutes is required.

Comment: A commenter stated that continuing to document the behavioral health services delivered and patient interactions associated with billing the add-on codes was unnecessarily burdensome and recommended that we allow practitioners to attest that they have the ability to provide integrated behavioral health services without documenting each required element of the service.

Response: We appreciate the commenter for the feedback and acknowledge that some administrative burden remains to bill the proposed add-on codes. However, at this time, we continue to believe that it is important that the elements of the particular add-on service are documented in the medical record, though we may consider this comment in future rulemaking.

Comment: A few commenters expressed concern that the creation of add-on codes would be confusing and unnecessarily burdensome when similar, standalone CPT codes already exist. The commenters suggested that we work with the American Medical Association to remove the time-based thresholds for the associated CPT codes: 99492, 99493, and 99484. Additionally, a few commenters questioned why we had not created an add-on code based on CPT code 99494.

Response: We appreciate the commenters for the suggestion. While we understand that there is always a learning curve when new HCPCS codes are introduced, we continue to believe that removing the time-based requirements for HCPCS codes G0568, G0569, and G0570 when billed in conjunction with an APCM base code (HCPCS codes G0556, G0557, and G0558) will ultimately reduce administrative burden, as it aligns the documentation requirements of the APCM codes with the add-on codes. The time-based requirements for CPT codes 99492, 99493, and 99484 remain in the instance these CPT codes are billed on a standalone basis, outside of the provision of APCM services.

3. Valuation of Behavioral Health Integration Add-on Codes for APCM Services

In consideration that the services described by the proposed add-on codes are meant to be directly comparable to the existing CoCM and BHI codes, we proposed a direct crosswalk to the current work RVU values of CPT code 99492 for HCPCS code G0568 (work RVU 1.88), CPT code 99493 for HCPCS code G0569 (work RVU 2.05), and CPT code 99484 for HCPCS code G0570 (work RVU 0.93). We also proposed a direct crosswalk to the current direct PE inputs for CPT codes 99492 (non-facility RVU 2.48, facility RVU 0.80), 99493 (non-facility RVU 1.93, facility RVU 0.86), and 99484 (non-facility RVU 0.66, facility RVU 0.30), to HCPCS codes G0568, G0569, and G0570, respectively. We solicited comments on this approach.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed their support for the proposed direct crosswalk to the current work RVU values and direct PE inputs to CPT code 99492 for HCPCS code G0568, CPT code 99493 for HCPCS code G0569, and CPT code 99484 for HCPCS code G0570. A commenter stated that instead of directly crosswalking the work RVU and direct PE inputs for the add-on codes, we should pay more than the current CPT codes.

Response: We appreciate the commenters for their responses to our proposal. In consideration that the services described by the proposed add-on codes are meant to be directly comparable to the existing CoCM and BHI codes, we continue to believe it is appropriate to directly crosswalk to the existing work RVUs and direct PE inputs for these services.

After consideration of the public comments, we are finalizing the establishment of three new G-codes to be billed as add-on services when the APCM base code (HCPCS codes G0556, G0557, and G0558) is reported by the same practitioner in the same month: HCPCS code G0568, an add-on code based on CPT code 99492 for an initial month of CoCM services delivered to patients also receiving APCM services, HCPCS code G0569, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and HCPCS code G0570, an add-on code for general behavioral health integration services based on CPT code 99484, and are finalizing the valuation of these codes as proposed.

4. Request for Information related to APCM and Prevention

Having a usual source of primary care can be positively associated with better receipt of recommended prevention services[78] and effective management of chronic disease,[79] which per the Trump Administration's Executive Order, "Establishing the President's Make America Healthy Again Commission,"[80] is a top priority for CMS. APCM coding and payment has represented CMS' recent efforts to promote team-based primary care. In the CY 2025 PFS final rule (89 FR 97863), commenters recommended that cost sharing be eliminated for APCM services, indicating that any amount of cost sharing could be prohibitive and may limit the uptake of APCM services. A few commenters suggested that APCM services are preventive services that should be exempt from beneficiary cost sharing.

At the time, we responded to comments stating that CMS did not see how APCM fit within the benefit categories for preventive services. After further consideration and analysis, there are some service elements of APCM that are substantively similar to certain aspects of the "personalized prevention plan

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[78] Blewett, Lynn, Pamela Jo Johnson, Brian Lee, and Peter Scal. When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services. Journal of General Internal Medicine. Volume 23, pages 1354-1360. Published May 28, 2008.

[79] Luo, Jiajun, Muhammad Kibriya, Paul Zakin, Andrew Craver, Liz Connellan, Saira Tasmin, Tamar Polonsky, Karen Kim, Habibul Ahsan, Briseis Aschebrook-Kilfoy. "Urban Spatial Accessibility of Primary Care and Hypertension Control and Awareness on Chicago's South Side: A Study From the COMPASS Cohort. Circ Carvdiovasc Qual Outcomes. 2022 Sep; 15(9):e008845. Doi: 10.1161/CIRCOUTCOMES.121.008845. Epub 2022 Sep 6.

[80] https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/

services" described under section 1861(hhh)(1) of the Act. For example, the personalized prevention plan includes a health risk assessment, which includes identification of chronic diseases, injury risks, modifiable risk factors, and urgent health needs. This is substantively similar to the service element of APCM that requires an overall systematic needs assessment (which includes both medical and psychosocial needs). The personalized prevention plan includes "improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management," which is substantively similar to the APCM service element of "oversight of self-management." However, as APCM is a bundle of different care management and communication technology-based services, there are other service elements of the APCM codes that may be covered under Medicare Part B and carry cost sharing obligations.

The blending of prevention and treatment services makes intuitive sense for those familiar with advanced primary care practices, which must simultaneously balance ensuring patients receive their needed preventive services and treatment services. Indeed, effective care management often means balancing prevention and treatment in the life an individual patient. For example, for a patient with a recent history of a Deep Venous Thrombosis (DVT) on anticoagulation medication, a primary care team must often balance whether or not to hold the patient's anticoagulation in order for the patient to receive a colonoscopy (where removal of a polyp while the patient is on anticoagulation can lead to excessive bleeding).[81] The primary care team must balance the relative risks of holding the anticoagulation medication, with the relative risks of delaying cancer screening, for the optimal health and wellbeing of the patient.

Given these factors, we solicited comments on how CMS should consider the application of cost sharing for APCM services, particularly, if we were to include preventive services within the APCM bundles. How should we account for cost sharing if APCM includes both preventive services and other Part B services? Should CMS consider including the Annual Wellness Visit, depression screening, or other preventative services in the APCM bundle, and if so, which services and why?

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[81] O'Donnel, Michael and Seth A. Gross. "Management of Anticoagulation and Colonoscopy." Current Treatment Options in Gastroenterology. Volume 19, pages 1-13(2021). Published January 16, 2021.

Should CMS consider other changes to APCM or additional coding to further recognize the work of advanced primary care practices in preventing and managing chronic disease?

Additionally, we have often described how primary care teams are central to the relative success of Medicare Shared Savings ACOs. In 2023, as in previous years, ACOs comprised of larger proportions of primary care clinicians had significantly higher net per capita savings than ACOs comprised of smaller proportions of primary care clinicians.

Should CMS consider new payments to Shared Savings Program ACOs for prospective monthly APCM payments to be delivered to primary care practices that satisfy the APCM billing requirements, with the payments reconciled under the ACO benchmark?

If so, how should CMS consider consent and other features of APCM in these contexts? Should CMS consider other updates to APCM payments or Shared Savings Program policies that would drive increased participation of primary care practitioners in ACOs?

We received public comments on this solicitation.

While we appreciate the commenters for their feedback, we will take the comments into consideration for possible future rulemaking.

H. Outpatient Therapy Services and KX Modifier Thresholds

In the CY 2026 PFS proposed rule, we inadvertently omitted the following section regarding Outpatient Therapy Services and KX Modifier Thresholds. However, we included this section as part of the CY 2026 PFS correcting document (90 FR 39158).

1. Technical Correction (§ 410.62(a))

In the CY 2009 PFS final rule (73 FR 69874 through 69875) we finalized the addition of a new paragraph at § 410.62(c) for the services of speech-language pathologists (SLPs) in private practice (SLPPPs) allowed through the amendments in section 143 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA); and, we also finalized a new condition of payment at § 410.62(a)(3)(ii) requiring these SLPPPs to meet the qualifications of SLPs at 42 CFR part 484 that is specified in the basic rule for outpatient speech-language pathology services at § 410.62(a).

During a recent review of the regulations at § 410.62, we noticed an error in § 410.62(a). That is, the basic rule at § 410.62(a) does not correctly reflect the policy that for Medicare Part B to pay for outpatient speech-language pathology services, those services are required to be delivered only by SLPs ─ including the SLPPPs specified at paragraph (a)(3)(ii) ─ meeting the requirements for an SLP at § 484.115. Instead, § 410.62(a) states that except as specified in paragraph (a)(3)(ii) of this section rather than paragraph (a)(3)(iii) which was paragraph (a)(3)(ii) before being redesignated as paragraph (a)(3)(iii) when the condition of payment was added for the services of SLPPPs. We inadvertently did not update the exception paragraph during CY 2009 PFS rulemaking to reflect the correct policy under which the individual furnishing services incident to the services of physicians, physician assistants (PAs), clinical nurse specialists (CNSs), or nurse practitioner (NPs) does not have to meet the state licensure requirement at § 484.115 (although they are required to meet the other standards and conditions that apply to SLPs). Therefore, we proposed to revise § 410.62(a) to reflect the policy related to qualifications for individuals furnishing services incident to the services of physicians, PAs, CNSs, and NPs by correctly referencing paragraph (a)(3)(iii) in place of paragraph (a)(3)(ii). We also proposed to make a conforming regulatory change at § 410.26(c)(2) to refer readers to § 410.62(a)(3)(iii) instead of § 410.62(a)(3)(ii) for the correct policy related to the qualifications for individuals providing speech-language pathology services furnished incident to the services of physicians, PAs, CNSs, and NPs.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

2. KX Modifier Thresholds

The KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, February 9, 2018) (BBA) and were formerly referred to as the therapy cap amounts. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2026, we proposed to increase the CY 2025 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2026, the proposed MEI increase is estimated to be 2.7 percent and is based on the expected historical percentage increase of the 2017-based MEI. Multiplying the CY 2025 KX modifier threshold amount of $2,410 by the proposed CY 2026 percentage increase in the MEI of 2.7 percent ($2,410 x 1.027) and rounding to the nearest $10.00 results in a proposed CY 2026 KX modifier threshold amount of $2,480 for physical therapy and speech-language pathology services combined and $2,480 for occupational therapy services. We also proposed to update the MEI increase for CY 2026 based on historical data through the second quarter of 2025, and we proposed to use such data, if appropriate, to determine the final MEI percentage increase and the CY 2026 KX modifier threshold amounts in the CY 2026 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 through CY 2027. Effective beginning with CY 2028, the MR threshold levels will be annually updated by the percentage increase in the MEI, per section 1833(g)(7)(B) of the Act. Consequently, for CY 2026, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

- The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.
- The therapy provider has a billing pattern for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.
- The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.
- The services are furnished to treat a type of medical condition.
- The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount for services of CMS designated "always therapy" services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceed one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

We received public comments on these updates. The following is a summary of the comments we received and our responses.

Comment: A commenter stated their appreciation of issuing the KX modifier threshold amounts and the MR threshold amount for CY 2026.

Response: We appreciate the commenter for their remarks.

Comment: A commenter requested that we issue the CY 2026 KX modifier thresholds in time to ensure consistent education by the A/B MACs that they believe will reduce claim denials and simplify the therapist's care planning.

Response: We would like to clarify that the A/B MACs are notified through our usual subregulatory change management process allowing them sufficient time to update the allowed dollar amount for CY 2026 outpatient KX modifier thresholds to $2,480. As such, claims from providers or therapists for therapy services above the CY 2026 KX modifier threshold amounts will not be denied unless the provider does not believe them to be medically necessary and foregoes the inclusion of the KX modifier on the claim for services as is appropriate.

We stated in the correction notice to the CY 2026 PFS proposed rule that we would use the MEI update based on historical data through the second quarter of 2025 to determine the final MEI percentage increase and the CY 2026 KX modifier threshold amounts in the CY 2026 PFS final rule. Since the projected 2026 MEI update based on historical data through the 2nd quarter of 2025 remains at 2.7 percent, we are finalizing the CY 2026 KX modifier threshold amounts as proposed; that is $2,480 for physical therapy and speech-language pathology services combined and $2,480 for occupational therapy services.

I. Policies to Improve Care for Chronic Illness and Behavioral Health Needs

1. Updates to Payment for Digital Mental Health Treatment (DMHT) and Comment Solicitation on Payment Policy for Software as a Service (SaaS)

a. Updates to Payment for DMHT

In the CY 2025 PFS final rule (89 FR 97923 through 97928), we established Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. We use the term "DMHT device" to include the term digital cognitive behavioral therapy we used in prior rulemaking (88 FR 79012 through 79013) and in general to refer to software devices cleared, approved, or granted De Novo authorization by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health. We use the terms "behavioral health conditions" and "mental disorders" interchangeably and to mean psychiatric disorders as referenced in FDA regulation, 21 CFR 882.5801. This includes substance use disorders. The FDA definition of devices encompasses certain software intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.[82] As the field of innovative products including digital therapeutics and computerized behavioral therapy devices for behavioral health treatment develops and expands the FDA continues to apply a risk-based framework to review and classify computerized behavioral therapy devices.

Effective January 1, 2025, we finalized three HCPCS G-codes for DMHT devices, to be billed by physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness: G0552 *(Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan)*; HCPCS code G0553 *(First 20 minutes of monthly treatment management services directly related to the patient's therapeutic*

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[82] Sec. 201(h)(1) of the Federal Food, Drug, and Cosmetic Act.

use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month); and HCPCS code G0554 *(Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month. (List separately in addition to HCPCS code G0553))*. We note that in the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we inadvertently transcribed the code descriptors for HCPCS codes G0553 and G0554 with the wording we had proposed in the CY 2025 PFS proposed rule, rather than as refined and finalized (89 FR 97927).

Additionally, we finalized the conditions of payment for these codes. To be payable under the PFS, the DMHT device must have been cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or granted De Novo authorization by FDA and in each instance classified at 21 CFR 882.5801. In addition, the billing practitioner must incur the cost of the DMHT device furnished to the beneficiary, and the furnishing of the DMHT device must be incident to the billing practitioner's professional services in association with ongoing behavioral health treatment under a plan of care by the billing practitioner. Furthermore, we finalized that the billing practitioner must diagnose the patient with a mental health condition and prescribe or order the DMHT device. In the CY 2026 PFS proposed rule (90 FR 32352, 32503), we clarified that the patient must have a mental health condition diagnosis, but the billing practitioner does not need to be the practitioner who made the diagnosis. The patient could then use the DMHT device in settings according to how the device has been classified by FDA for use at 21 CFR 882.5801, which could include the home or an office or other outpatient setting if consistent with the FDA classification for use. Also, payment may only be made for DHMT devices for mental health treatment in accordance with the use indicated in their FDA classification at 21 CFR 882.5801. We continue to be vigilant about waste, fraud and abuse as we develop payment policy for devices that may

function like DMHT devices but whose technology platforms may differ from those of DMHT devices classified at 21 CFR 882.5801. We seek to ensure that DMHT devices are not only safe for patients but also beneficial for patients. Our objective in requiring that DMHT devices be classified at 21 CFR 882.5801 as a condition of payment was to set guardrails within our payment policy for patient safety and benefit. While partly in recognition of our inability to evaluate every DMHT device, in this way we limited payment to devices which are required to comply with the special controls requiring clinical data to validate the model of behavioral therapy as implemented by the device. While presently use cases for insomnia, substance use disorder, depression and anxiety have been classified by the FDA at 21 CFR 882.5801, future use cases are not necessarily limited to these. It is possible that additional DMHT devices for other use cases with similar characteristics may be classified under this code section.

As stated in the CY 2025 PFS final rule (89 FR 97926) and in the CY 2026 PFS proposed rule (90 FR 32503), updating our payment policies will be an iterative process relating first to behavioral health treatment and by extension to chronic conditions. Behavioral health conditions are some of the most prevalent chronic diseases in the country. Among adults aged 18 or older in 2023, 22.8 percent (or 58.7 million people) had any mental illness and 48.5 million people aged 12 or older (or 17.1 percent) had a substance use disorder (SUD) in the past year. These behavioral health conditions are often chronic in nature. Individuals with Major Depressive Disorder, for example, often have recurrent episodes throughout their lives.[83]

The technologies and platforms for digital therapeutics are evolving rapidly. We are at an early stage of Medicare payment for DMHT devices as supplies furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. In considering the next stage in the development of our payment policy, we have been reviewing interested parties' recommendations to make payment for FDA authorized devices under other classifications, including Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions under 21 CFR 876.5960; Biofeedback device under 21 CFR 882.5050; Digital therapy device to reduce sleep disturbance for psychiatric conditions under 21 CFR 882.5705; Digital therapy device for Attention Deficit Hyperactivity Disorder under 21 CFR 882.5803; and Computerized

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[83] https://www.samhsa.gov/data/sites/default/files/NSDUH%202023%20Annual%20Release/2023-nsduh-main-highlights.pdf.

behavioral therapy device for the treatment of fibromyalgia symptoms to be codified at 21 CFR 882.5804. We noted that Medicare coverage of biofeedback is limited by a long-standing national coverage determination. See, Medicare National Coverage Determinations Manual Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations, Section 30.1, Biofeedback, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part1.pdf.

We proposed to expand our payment policies for HCPCS codes G0552, G0553, and G0554 to also make payment for DMHT devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each instance classified at 21 CFR 882.5803, Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD). The 21 CFR 882.5803 classification is for software intended to provide therapy for ADHD or any of its individual symptoms as an adjunct to clinician supervised treatment. Comparable to the special controls for device classification 21 CFR 882.5801 Computerized behavioral therapy device for psychiatric disorders, the 21 CFR 882.5803 device classification's special controls require the use of a validated measure to evaluate effectiveness of the device to provide therapy for ADHD or any of its individual symptoms. The special controls for device classification 21 CFR 882.5801 require that clinical data must be provided to describe a validated model of behavioral therapy for the psychiatric disorder; and to validate the model of behavioral therapy as implemented by the device. Comparable to the 21 CFR 882.5801 device classification, the 21 CFR 882.5803 device classification is intended to provide therapy as an adjunct to clinician supervised treatment. We believe that it is important to expand our coding and payment policies to include such devices classified at 21 CFR 882.5803 to more fully reflect the range of behavioral health disorders treated by FDA-authorized products. We also proposed that all the conditions of payment for HCPCS codes G0552, G0553, and G0554 finalized in the CY 2025 PFS final rule (89 FR 97927) would apply to DMHT devices classified at 21 CFR 882.5803. These conditions of payment for DMHT device coding are that the billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary as a supply, that furnishing of the DMHT device is incident to the billing practitioner's professional services in association with ongoing behavioral health treatment under a plan of care by the billing practitioner, and that payment may only be made for DHMT devices for mental health treatment in accordance with the use indicated in their FDA classification (89 FR 97927).

Additionally, we solicited comments on whether we should establish coding and payment policies for devices classified under the following FDA regulation sections that were recommended to us by interested parties: Computerized behavioral therapy devices for treating symptoms of gastrointestinal conditions at 21 CFR 876.5960; Digital therapy devices to reduce sleep disturbance for psychiatric conditions at 21 CFR 882.5705; and Computerized behavioral therapy device for the treatment of fibromyalgia symptoms to be codified at 21 CFR 882.5804.

Medicare FFS claims data for HCPCS codes G0552, G0553, and G0554 have remained low in volume since we established these codes in the CY 2025 PFS final rule. We understand there may be several reasons for this. We are aware per interested parties and commenters that one of the conditions of payment that we established for these codes, that the billing practitioner is incurring the cost of furnishing the DMHT device to the patient, may not align with direct-to-consumer delivery and payment models that existed before the final rule was issued.

At this time, we do not believe we can appropriately price all the DMHT devices for which we would make payment under our current policies and proposals, and therefore, we did not propose any changes to the existing contractor-priced status for HCPCS code G0552. As we have noted, the technologies and DMHT therapies are evolving rapidly. We have recognized that our payment policy, too, will evolve. Given the dynamic nature of the development of these devices and the variation in methods of action for potential technology platforms, we do not have sufficient information needed to establish national pricing for devices described by HCPCS code G0552 at this time. We recognized that the ongoing nationwide behavioral health workforce shortage combined with increasing demand for behavioral health care services may limit access to behavioral health services for some Medicare beneficiaries.[84] We recognized that digital therapeutic devices may offer innovative means to access certain behavioral health care services. We acknowledged that the field of digital therapeutics is evolving and continue to solicit comments from the public on this topic, including the CPT Editorial Panel. We have continued to aim to both provide access to vital behavioral health services and to gather further information about the delivery of digital behavioral health therapies, their effectiveness, their adoption by practitioners as complements to the behavioral health care that they furnish, and their use by patients for

[84] https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand.

the treatment of behavioral health conditions. We have continued to seek information and may consider national pricing through future rulemaking.

We sought comments on the possibility of establishing for CY 2026 additional separate coding and payment for a broader based set of services describing digital tools used by practitioners intended for maintaining or encouraging a healthy lifestyle, as part of a mental health treatment plan of care. Specifically, we sought information about clinical practice involving use of such tools. On what reliable evidence do practitioners inform their clinical judgment that use of such digital tools is warranted or beneficial to their treatment of the patient? What role do these digital tools typically have within plans of behavioral health treatment? What appropriate crosswalks would we consider for the purposes of nationally pricing a code to describe digital tools that do not require FDA clearance, approval or authorization and therefore do not entail the development costs of FDA clearance, approval or authorization or meet other conditions of payment for HCPCS code G0552, primarily that the practitioner must bear the cost of the DMHT device as a supply incident to their services. For example, we could consider the inputs assigned to CPT code 98016 (Brief communication technology-based service (for example, virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5 to 10 minutes of medical discussion) or CPT code 99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5 to 10 minutes). Since the resource costs reflected in the practice expense should be lower for services involving digital tools that do not require FDA clearance, approval, or authorization or meet the condition of payment that the billing practitioner bears the cost of supplying the DMHT device for HCPCS code G0552, we anticipated that the corresponding valuation for any additional coding would be appropriately lower than G0552. We solicited comments on these potential crosswalks or any other services that may best approximate the resource costs involved in cases where practitioners furnish a digital tool as part of a mental health treatment plan of care and furnish initial education and onboarding, per course of treatment that augments a behavioral therapy plan, and monthly treatment management services directly related to the patient's

use of these digital tools. We also solicited comments on these potential crosswalks or any other services that may best approximate the resource costs involved in cases where practitioners do not furnish the digital tool and do not furnish initial education and onboarding for the tool but nonetheless incorporate use of the tool as part of a mental health treatment plan of care.

Additionally, we sought comments on other related digital device policies for our consideration in future rulemaking. Specifically, we received a request from an interested party to create a new add-on G code to existing CPT codes 96112, 96113, 96116, 96121, 96130, 96131, 96132, and 96133 (code descriptors can be found in Table A-I1), for physicians' or non-physician practitioners' psychological/neuropsychological evaluations so they may report administration of an FDA authorized eye-tracking technology to aid in the diagnosis of Autism Spectrum Disorder (ASD) in pediatric patients, including staff time with the patient, data submission and output.

The interested party stated that the device collects data based on the clinical presentation of a patient, then an analysis algorithm is applied to the collected data to generate output. The interested party raised concerns that currently there are delays and waitlists to obtain diagnostic evaluations for children at risk for ASD. Their solution is to use this ASD diagnosis tool at the point of care after a parent or physician identifies a risk of ASD in a child. According to the interested party, this digital device can help reduce ASD diagnosis delays to be seen by a diagnostic specialist. The interested party is requesting the following code descriptor, *Algorithm-driven neurological assessment for likelihood of Autism Spectrum Disorder (ASD) diagnosis, and of ASD-measures' severity (for example, social disability, verbal and non-verbal ability), derived from validated quantitative analysis of looking behavior,* and recommends for CMS to either establish a national rate for the add-on code using a crosswalk to CPT code 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), CPT code 93247 (External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report), or to allow contractor pricing.

We solicited comments from the public regarding whether creating an add-on G code and contractor pricing is needed for the administration of an FDA authorized eye-tracking technology and other technology to aid in the diagnosis of ASD in pediatric patients; or whether it would be more

appropriate to go through the CPT Editorial Panel process to obtain a Category III CPT code for this treatment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters reported inconsistency among Medicare Administrative Contractors (MACs) in setting payment rates for HCPCS code G0552. Many of these commenters stated that they believe uncertainty among practitioners about adequate payment has resulted in a barrier to practitioners' adoption of this technology. The overwhelming majority of these commenters recommended that we adopt a national rate for HCPCS code G0552. Other commenters recommended that CMS provide guidance to the MACs regarding the appropriate considerations for evaluating the medical necessity of a DMHT device and for establishing pricing data sources specific to DMHT devices. They also recommended that CMS instruct the MACs to develop a timely and transparent process for claims review and require that individuals with behavioral health expertise be involved in the coverage determination and claims review processes.

Response: We appreciate the commenters for their recommendations. In response to the comments, we will work with the CMS MACs to improve the understanding of the billing rules for HCPCS code G0552. As we stated in the CY 2025 PFS final rule (89 FR 97928), we still do not believe that we have enough information to appropriately price all the DMHT devices for which we propose to make payment. As we have noted, the technologies and DMHT therapies are evolving rapidly. Given the dynamic nature of the development of these devices and the variation in methods of action for potential technology platforms, we do not have sufficient information needed to establish national pricing for devices under HCPCS code G0552 at this time. However, we continue to welcome information on this and may consider national pricing through future rulemaking.

Comment: Many commenters made specific comments about our proposal to make payment for DMHT devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each instance classified at 21 CFR 882.5803, Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD). The majority of commenters supported this proposal. Some commenters

opposed including devices from any other FDA classification in addition to devices classified at 21 CFR 882.5801 as finalized in the CY 2025 PFS final rule.

The commenters stated that adding more devices under HCPCS code G0552 would lead to a misleading code descriptor, confusion for the provider community with uncertainty about which devices would be payable, imprecise valuations, and increased variability in pricing among the MACs. These commenters instead suggested that CMS assign a national price for all devices under HCPCS code G0552. Others were opposed to allowing payment of devices specifically classified at 21 CFR 882.5803, Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD) because they believe these devices were not representative of the Medicare population.

Response: We appreciate commenters for their feedback. As we stated in the CY 2026 PFS proposed rule, we believe that it is important to expand our coding and payment policies to include such devices classified at 21 CFR 882.5803 to more fully reflect the range of behavioral health disorders treated by FDA-authorized products. The classification at 21 CFR 882.5803 is for software intended to provide therapy for ADHD or any of its individual symptoms as an adjunct to clinician supervised treatment. Comparable to the special controls for device classification under 21 CFR 882.5801, Computerized behavioral therapy device for psychiatric disorders, the 21 CFR 882.5803 device classification's special controls require the use of a validated measure to evaluate effectiveness of the device to provide therapy for ADHD or any of its individual symptoms. The special controls for device classification under 21 CFR 882.5801 require that clinical data must be provided to describe a validated model of behavioral therapy for the psychiatric disorder; and to validate the model of behavioral therapy as implemented by the device. Comparable to the 21 CFR 882.5801 device classification, the 21 CFR 882.5803 device classification is intended to provide therapy as an adjunct to clinician supervised treatment. We believe it is appropriate to group these devices under a single HCPCS code, G0552. We are finalizing payment for DMHT devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each instance classified at 21 CFR section 882.5803, Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD), as proposed. Furthermore, we are clarifying here that the patient must have a mental health condition diagnosis, but the billing practitioner does not need to be the practitioner who made the diagnosis. As proposed, all HCPCS code G0552 billing requirements

applicable to devices classified at 21 CFR 882.5801 will be applicable to devices classified at 21 CFR 882.5803, that is:

- The billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary as a supply,
- That furnishing of the DMHT device is incident to the billing practitioner's professional services in association with ongoing behavioral health treatment under a plan of care by the billing practitioner, and
- Payment may only be made for DHMT devices for mental health treatment in accordance with the use indicated under their FDA classification.

Comment: Many commenters recommended CMS to expand the number of devices payable under our DMHT payment policy, HCPCS code G0552, to include, "Computerized behavioral therapy devices for treating symptoms of gastrointestinal conditions" classified under 21 CFR 876.5960; and for "Computerized behavioral therapy device for the treatment of fibromyalgia symptoms" to be codified at 21 CFR 882.5804. A few commenters offered their support for making payments for "Digital therapy devices to reduce sleep disturbance for psychiatric conditions" classified under 21 CFR 882.5705. The commenters, who did not mention these devices' classifications, suggested instead expanding coding and payment for digital treatment of mental health and medical conditions through alternative approaches. Some suggested the creation of a code specific to each device, others suggested developing future coding according to device indications, others suggested coding by FDA classification, others suggested relying on CPT coding, and others suggested payment for devices under bundled services. Some commenters further suggested various criteria or processes by which to evaluate and decide which devices to make eligible for payment. Some commenters offered their suggestions for approaching coverage determinations.

Response: We appreciate commenters who responded to our solicitation regarding whether we should establish coding and payment policies for devices classified under the three FDA regulations discussed earlier. At this time, we are not further expanding payment under our DMHT payment policy. We will continue to solicit input from interested parties for coding and payment policies to expand

payment for FDA cleared and authorized digital mental health treatment devices. We may consider expanding our payment policy to include them under future rulemaking.

Comment: Many commenters were opposed to the possibility of establishing for CY 2026 additional separate coding and payment for a broader based set of services describing digital tools used by practitioners intended for maintaining or encouraging a healthy lifestyle, as part of a mental health treatment plan of care. These commenters believe that no payment should be made for digital tools which have not been cleared or authorized by the FDA as devices. A few commenters stated they were encouraged by our comment solicitation and shared how they believe clinical practices may rely on information to form clinical judgments about using such digital tools and whether such use may be warranted and beneficial to patient care. Some commenters expressed concern that we intended to finalize payment for these tools under HCPCS code G0552.

Response: We appreciate all the comments we received. At this time, after consideration of all these comments we are not finalizing any new coding and payment for such digital tools. To reiterate, HCPCS code G0552 makes payment available for the supply of digital mental health treatment devices and initial education and onboarding, per course of treatment that augments a behavioral therapy plan. Devices paid for under HCPCS code G0552 must be cleared or authorized by the FDA and classified under either 21 CFR 882.5801, or beginning January 1, 2026, under 21 CFR 882.5803.

Comment: We received public comments on the comment solicitation regarding whether creating an add-on G code and contractor pricing is needed for the administration of an FDA authorized eye-tracking technology and other technology to aid in the diagnosis of ASD in pediatric patients; or whether it would be more appropriate to go through the CPT Editorial Panel process to obtain a Category III CPT code for this treatment.

Response: We appreciate the commenters for their comments. After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

TABLE A-I1: PSYCHOLOGICAL/NEUROPSYCHOLOGICAL EVALUATION CODES

CPT Code	Long Descriptor
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour

CPT Code	Long Descriptor
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [for example, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [for example, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)

b. Comment Solicitation on Payment Policy for Software as a Service (SaaS)

In recent years, there have been rapid developments in the use of software-based technologies to support clinical decision-making in the outpatient and physician office settings, some of which may be devices requiring FDA, clearance, approval, or authorization. We refer to these software-based technologies as software as a service (SaaS). As the data used in our PE methodology has aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology. As described in section II.B of this final rule, PE resources typically involved in furnishing services are characterized as either direct or indirect costs. Direct costs involved in furnishing a service are estimated for each code and include clinical labor, medical supplies, and medical equipment. Indirect costs include administrative labor, office expenses, and all other expenses. Indirect PE is allocated to each service based on physician work, direct costs, and a specialty-specific indirect percentage. The source of the specialty specific indirect percentage

was the Physician Practice Information (PPI) Survey, last administered in 2007 and 2008, when emerging technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware, may not have been typically used in furnishing services at that time. Thus, these costs are not well accounted for in the PE methodology. While we have received updated PPI survey data from the AMA that did incorporate information on the practice costs associated with SaaS and AI services, this information would only reflect the impact of SaaS and AI on the PE/hr associated with a given medical specialty, rather than providing insight into the direct costs associated with use of this technology.

Furthermore, as described in section II.B.5. of this final rule, due to several limitations with the data, we did not propose to implement the PE/HR data or cost shares from the AMA's PPI Survey data for CY 2026 ratesetting. Consistent with our PE methodology and as we have stated in past PFS rulemaking (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment. However, beginning with payment for Fractional Flow Reserve Computed Tomography (Heartflow) in the CY 2022 PFS final rule (86 FR 65041) CMS has made intermediate, service-specific policies to allow for PFS payment of SaaS and AI applications in certain circumstances. CMS has made intermediate, service-specific policies to allow for PFS payment of SaaS and AI applications in certain circumstances.

We consider several distinct issues when evaluating SaaS technologies. First, we have observed wide variations in the purported costs of clinically similar SaaS technologies. The various costs that manufacturers consider when pricing their technologies, including research and development and software maintenance, are often not publicly verifiable. Additionally, due to the novel and evolving nature of these technologies, there are rarely existing medical items or services that can be utilized for comparison purposes to determine clinical and resource similarity. Finally, while there has been a rapid increase in the development and coding of services incorporating these technologies in recent years, there is a very limited amount of Medicare claims data for these services.

As this technology has continued to evolve and diversify, interested parties have stated that the lack of a consistent payment policy for SaaS and AI devices is an impediment to patient access when these devices are otherwise cleared, approved, or authorized by the FDA. Interested parties have

requested that CMS consider the development of a payment policy for these devices that is stable and consistent across settings of care, payment systems, and types of services incorporating SaaS and AI devices. Additionally, as we are interested in paying accurately for the management of chronic disease and primary care services, we sought to understand how the use of SaaS and AI technology affects those services and how to incorporate these costs into our current strategy for paying for evolving models of care delivery, such as Advanced Primary Care Management and risk-based payment arrangements generally. Therefore, we solicited public comments on how we should consider paying for SaaS under the PFS, including:

- What factors should we consider when paying for SaaS?
- What has the experience been of risk-based payment arrangement participants with incorporating SaaS under their payment arrangements?
- Have risk-based payment arrangements reflected the underlying value of SaaS to the practice of medicine?
- Given the limitations of the PE methodology to account for this kind of technology, what alternative pricing strategies should CMS use to accurately pay for SaaS and AI devices under the PFS? For example, should CMS continue its current practice, as referenced in section II.E.23. of this final rule, of crosswalking values from the OPPS established payment amounts for the technical components of services incorporating SaaS and AI? Or should we integrate OPPS geometric mean costs for these devices into our ratesetting methodology as we proposed to do in this final rule for RPM and RTM services, or set payment rates relative to OPPS rates as we are proposing to do for radiation oncology services? See sections II.E.24. and 30. this final rule.
- How should CMS value the physician work associated with utilizing and interpreting the clinical outputs associated with SaaS and AI devices?
- Is there an alternative data source outside of the limited Medicare claims data currently available and hospital invoices provided by manufacturers, which may not fully depict total hospital acquisition costs, that can accurately reflect the costs of the SaaS?
- How are these technologies used in the treatment of chronic disease?
- How may CMS best evaluate the quality and efficacy of SaaS and AI technologies?

We welcomed input in the proposed rule from interested parties on these questions as well as any additional suggestions that would enhance our ability to provide accurate and consistent payment for procedures incorporating SaaS. We noted that there is a comment solicitation in the CY 2026 OPPS proposed rule regarding SaaS devices furnished in hospital outpatient departments and ASCs.

We received public comments on this comment solicitation on how we should consider paying for SaaS under the PFS.

After consideration of public comments, we express appreciation for the feedback from commenters and may consider them for possible future rulemaking.

2. Prevention and Management of Chronic Disease – Request for Information

Six in ten Americans have at least one chronic disease, and four in ten have two or more chronic diseases. Many preventable chronic diseases are caused by a short list of risk behaviors, including smoking, poor nutrition, physical inactivity, and excessive alcohol use.[85] In 2023, among adults aged 18 or older, 22.8 percent (or 58.7 million people) had any mental illness (AMI) in the past year.[86] Although Medicare Part B covers many preventive services[87], as defined in section 1861(ddd)(3) of the Act, Medicare preventive services have some restrictions.[88]

Per the Trump Administration Executive Order, "Establishing the President's Make America Healthy Again Commission,"[89] the Administration is directing our focus towards understanding and drastically lowering chronic disease rates, including thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety. Furthermore, the Executive Order directs that agencies must ensure the availability of expanded treatment options and the flexibility for health insurance coverage to provide benefits to support beneficial lifestyle changes and disease prevention. As such, focusing on the prevention and management of chronic disease is a top priority for us.

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[85] Centers for Disease Control. "Chronic diseases in America." Available from: https://www.cdc.gov/chronic-disease/about/index.html#:~:text=Six%20in%2010%20Americans%20have,inactivity%2C%20and%20excessive%20alcohol%20use.
[86] Highlights for the 2023 National Survey on Drug Use and Heath, https://www.samhsa.gov/data/sites/default/files/NSDUH%202023%20Annual%20Release/2023-nsduh-main-highlights.pdf.
[87] https://www.medicare.gov/coverage/preventive-screening-services.
[88] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c18pdf.pdf
[89] https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.

We sought feedback to help us better understand how we could enhance our support management for prevention and management of chronic disease. Specifically, we sought commenters consider the following information:

- How could we better support prevention and management, including self-management, of chronic disease?
- Are there certain services that address the root causes of disease, chronic disease management, or prevention, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? If so, please provide specific examples.
- Are there current services being performed to address social isolation and loneliness of persons with Medicare, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? If so, what evidence has supported these services, and what do these services entail? What services have been delivered by Medicare providers or community-based organizations, including area agencies on aging and other local aging and disability organizations? What has been the impact?
- Are there current services being performed that improve physical activity, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set? How should CMS consider provider assessment of physical activity, exercise prescription, supervised exercise programs, and referral, given the accelerating use of wearable devices and advances in remote monitoring technology?
- Should CMS consider creating separate coding and payment for intensive lifestyle interventions, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set, and how should these interventions be prioritized? If so, what evidence has supported these services, and what do the services entail? How would additional coding and payment be substantively different from coding and payment for Intensive Behavioral Therapy?
- Should CMS consider creating separate coding and payment for medically-tailored meals, as an incident-to service performed under general supervision of a billing practitioner? If so, what would be the appropriate description of such a service, and under what patient circumstances (that is, after discharge from a hospital)? Do community-based organizations providing medically tailored meals

currently employ a physician, nurse practitioner, physician assistant, or other practitioner who could both bill Medicare and supervise a medically-tailored meal service? Should CMS consider allowing billing providers to refer to community-based organizations to deliver and ensure quality of medically-tailored meals while under general supervision (please see § 410.26(a)(3) for further information about general supervision) of the referring billing provider? If CMS were to create separate coding and payment for medically-tailored meals, how should CMS ensure integrity of the service being delivered?

- Please provide information on whether we should consider creating separate coding and payment for FDA-cleared digital therapeutics that treat or manage the symptoms of chronic diseases an incident-to service performed under the general supervision of a billing practitioner. Please see the CY 2025 PFS final rule (89 FR 97923 through 97928) for reference as to how we created new coding and payment for FDA-cleared digital mental health treatments (DMHTs).
- Are there technical solutions that would enhance the uptake of the annual wellness visit (AWV), or the improving accessibility, impact, and usefulness of the AWV? How can CMS better support practitioners and beneficiaries related to the AWV? Should CMS consider moving some of the required components of the AWV to optional add-on codes of the AWV instead, with the intent of decreasing burden, improving uptake, and allowing practitioners to select additional AWV elements that may be more relevant to particular patients?
- The Administration for Community Living (ACL) has defined evidence-based programs,[90] which have demonstrated impact in effectively treating chronic disease, preventing disease, and helping older adults and people with disabilities to adopt healthy behaviors, improve their health status, reduce disability and injury, and reduce their use of hospital services and emergency room visits. In addition to programs impacting chronic disease management and prevention, there are evidence-based health programs that address older adult falls, mental health, physical activity, and more. Fifty-six State units on aging that work with over 600 area agencies on aging (AAAs) and their networks of service providers receive formula grants from ACL to administer programs, but the need exceeds available federal funding. Are there certain existing or new Physician Fee Schedule codes and payment, or Innovation Center Models, that could better support practitioner provision of successful interventions through partnerships

[90] Administration for Community Living. "Health Promotion." https://acl.gov/programs/health-wellness/disease-prevention

between health care entities, AAAs, community care hubs, and other local aging and disability organizations? If so, please provide specific examples.

- In consideration that there are significantly more types of coding and payment that describe procedures in the physician fee schedule, please provide feedback regarding whether this detracts from the codes describing services that address underlying health behaviors, chronic disease management, and prevention.

Aligning with this initiative to focus on the prevention and management of chronic disease, we are considering whether to create additional coding and payment for motivational interviewing. Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific health goal and exploring the person's own reasons for change within an atmosphere of acceptance and compassion.[91] Compared to traditional advice-giving, motivational interviewing is more successful at improving a patient's underlying health behaviors that contribute to chronic disease, including but not limited to smoking, substance use, physical activity, nutrition, and adherence to medication and other treatments. Multiple meta-analyses have demonstrated that motivational interviewing has demonstrated statistically significant improvements in reduction of alcohol consumption, reduction in substance use in people with dependency or addiction, increased physical activity participation,[92] increased weight loss, and reduction in blood pressure.[93] Motivational interviewing has been adapted and integrated into many settings, including primary care facilities, emergency departments, behavioral health centers, and criminal justice and social service agencies.[94] We considered whether to develop separate coding and payment for motivational interviewing, which could also be performed under general supervision of the billing practitioner, in order to better account for the time and resources involved in furnishing this care. Furthermore, we understand that in many practices, health coaches can help support the provision of motivational interviewing services. We noted that the Category

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[91] Miller, W.R. & Rollnick, S. (2013) Motivational Interviewing: Helping people to change (3rd Edition). Guilford Press.

[92] Frost, Helen et al. "Effectiveness of Motivational Interviewing on Adult Behaviour Change in Health and Social Care Settings: a Systematic Review of Reviews." Available from: https://pubmed.ncbi.nlm.nih.gov/30335780/.

[93] VanBuskirk, Katherine, Julie Loebach Wetherell. "Motivational interviewing with primary care populations: a systematic review and meta-analysis." Available from: https://pubmed.ncbi.nlm.nih.gov/23934180/.

[94] SAMHSA, Treatment Improvement Protocol 35: Enhancing Motivation for Change in Substance Abuse Treatment Updated 2019, https://library.samhsa.gov/sites/default/files/tip-35-pep19-02-01-003.pdf.

III CPT codes (0591T, 0592T, and 0593T) for health coaching are currently contractor-priced, and have a January 2030 sunset date. However, health coaches do not have a Medicare benefit category and therefore cannot bill Medicare directly (a new benefit category requires statutory change) but could potentially operate as clinical staff under general supervision incident-to a physician service if new coding and payment were constructed in this way.

We solicited comments from the public regarding motivational interviewing and health coaches. Specifically, we requested that commenters consider the following information:

- Please provide information on whether we should create separate coding and payment for motivational interviewing, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment.
- What is the best definition and description of motivational interviewing?
- What types of clinical staff should be able to perform motivational interviewing under the general supervision of a billing practitioner?
- How long does a session of motivational interviewing typically last? If we were to create coding and payment for motivational interviewing, what should the time-based requirements of the code be?
- We heard from interested parties that in many clinics, health coaches perform services under general supervision, and that there may be substantive overlap with motivational interviewing. To what extent are the services performed by health coaches encompassed by motivational interviewing?
- What training is required to effectively perform motivational interviewing? Are there agreed upon national training or certification standards for health coaches? If so, what are they? Do states have separate training or certification standards for health coaches?
- To what extent would health coaches be able to perform motivational interviewing incident-to billing practitioners under general supervision? Please see § 410.26(a)(3) for further information about general supervision.
- In what clinical situations are motivational interviewing and health coaching most commonly performed? What are the clinical characteristics of a patient where motivational interviewing and health coaching would be medically reasonable and necessary?

- Can motivational interviewing and health coaching appropriately be performed via audiovisual or audio-only synchronous telecommunication?
- What has been the experience of providers and payers utilizing the codes 0591T (Health and well-being coaching: face-to-face, individual initial assessment), 0592T (Individual follow-up session, at least 30 minutes), and 0593T (Group session, two or more individuals, at least 30 minutes)? If the CPT committee were to create permanent codes with staff able to operate under the general supervision of a billing practitioner, would this capture the time and resources to perform health coaching?
- To what extent would new coding for motivational interviewing or health coaching better support some of the evidence-based programs funded and overseen by ACL that effectively manage or prevent chronic disease?

We welcomed feedback from interested parties and the public on how we could better support management of chronic disease and prevention, including whether we should create separate coding and payment for motivational interviewing, along with overlap between motivational interviewing and health coaches for consideration for future rulemaking.

We received public comments on this comment solicitation on how we could better support management of chronic disease and prevention, including whether we should create separate coding and payment for motivational interviewing, along with overlap between motivational interviewing and health coaches for consideration for future rulemaking.

After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

3. Community Health Integration and Principal Illness Navigation for Behavioral Health

a. Practitioner Types

In the CY 2024 PFS final rule (88 FR 78920), we finalized G-codes to reflect new coding and payment for services describing Community Health Integration (CHI) services (HCPCS codes G0019 (*Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month*) and G0022 (*Community health integration services, each additional 30 minutes per calendar month*)), provided by certified or trained auxiliary personnel, including a community health

worker, under the direction of a physician or other practitioner. We also finalized Principal Illness Navigation (PIN) services (HCPCS codes G0023 (*Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month*) and G0024 (*Principal Illness Navigation services, additional 30 minutes per calendar month*); G0140 (*Principal Illness Navigation—Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month*) and G0146 (*Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month*)), provided by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist. In the CY 2025 PFS final rule (89 FR 97822), we clarified that when we refer to "certified or trained auxiliary personnel" in the following codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes clinical social workers (CSWs).

Marriage and family therapists (MFTs) and mental health counselors (MHCs) have a similar statutory benefit category as CSWs and may also connect individuals with community-based resources to address unmet social needs that affect the diagnosis and treatment of medical problems. Like CSWs, MFTs and MHCs can bill Medicare directly for services they personally perform for the diagnosis or treatment of mental illness and substance use disorders, but are not authorized by statute to bill under the PFS for services that are provided by auxiliary personnel incident to their professional services. CHI and PIN services are typically provided by auxiliary personnel supervised by the billing practitioner, and MFTs and MHCs could serve as auxiliary personnel, as the codes do not limit the types of auxiliary personnel that can perform CHI and PIN services incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1). MFTs and MHCs could not directly bill Medicare under the PFS for CHI and PIN services if they were provided by auxiliary personnel, as they are not authorized to supervise, bill, and be paid directly by Medicare for services that are provided by auxiliary personnel incident to their professional services. As we stated previously in the CY 2024 PFS final rule (88 FR 78926), the codes do not limit the types of other health care professionals, such as registered nurses and social workers, that can perform CHI services (and PIN services, as we discuss in

the next section) incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1). We are clarifying that when we refer to "certified or trained auxiliary personnel" in the following HCPCS codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes MFT and MHCs. We are clarifying that, like CSWs, MFTs and MHCs can bill Medicare directly for CHI and PIN services they personally perform for the diagnosis or treatment of mental illness. Additionally, CMS required for auxiliary personnel performing CHI and PIN under general supervision, that in the absence of state level certification or training requirements, CMS required training to perform the services. We further clarified that if CSWs, MFTs, and MHCs are performing the services as auxiliary personnel under the general supervision of a billing practitioner, in the absence of state-level requirements, that they meet the certification or training requirements to perform all CHI and PIN service elements. This is relevant in the cases where a CSW, MFT, or MHC are performing CHI and PIN under the general supervision of a billing practitioner for a medical problem that is not considered a mental illness. For CHI and PIN services, as with all incidents to services, it is the billing practitioner's responsibility to ensure that all payment rules and applicable State requirements are met including licensure, certification, and/or training. This does not mean that the billing practitioners are required to provide the licensure, certification, and/or training themselves, but rather that they must ensure that the Medicare criteria for billing and payment of CHI and PIN services are met.

Individuals who personally furnish or serve as auxiliary personnel for CHI and PIN services must meet all other service requirements associated with these codes. We solicited comments on this clarification.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our clarification, stating that behavioral health practitioners, including CSWs, MFTs, and MHCs, meet the necessary certification and training to deliver all CHI and PIN service elements. The commenters informed us that this clarification is a meaningful step toward expanding workforce capacity that may assist in reducing care bottlenecks and enhancing patient access to much needed support.

Response: We appreciate the commenters for their feedback.

Comment: Some commenters requested that we further broaden the scope of auxiliary personnel to include other professionals that were not explicitly named in this clarification.

Response: As we stated previously in the CY 2024 PFS final rule (88 FR 78926), the codes do not limit the types of other health care professionals, such as registered nurses and social workers, that can perform CHI services (and PIN services, as we discuss in the next section) incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1).

After consideration of public comments, we are finalizing as proposed.

b. Initiating Visits

In the CY 2024 PFS final rule (88 FR 78923), we finalized allowing E/M services (other than a low-level E/M visit done by clinical staff), including an E/M service that is part of a transitional care management (TCM) service and an annual wellness visit (AWV) service to serve as the initiating visit for CHI services. We received comments requesting for CPT codes 90791 (Psychiatric diagnostic evaluation) and 96156 (Health behavior assessment, or re-assessment (that is, health-focused clinical interview, behavioral observations, clinical decision making)) to be allowed to serve as initiating visits, but we determined at the time that these services would be better captured and better serve the needs being addressed with the PIN service elements. We have continued to analyze the uptake of CHI services and believe that these services may fit the need for additional initiating CHI visits, as utilization data is showing that CHI services are being used to address SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat mental illness.

For CSWs, MFTs, and MHCs to bill Medicare directly for CHI services personally performed for the diagnosis or treatment of mental illness, we proposed in the CY 2026 PFS proposed rule to allow for CPT code 90791 (Psychiatric diagnostic evaluation) or the Health Behavior Assessment and Intervention (HBAI) services that CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 (and any subsequent HBAI codes) to serve as initiating visits for CHI, as we believe these codes are the most analogous codes to the E/M codes that are currently used as initiating visits for CHI that are utilized by practitioners in a specialty whose covered services are limited by statute to services for the diagnosis and

treatment of mental illness. All other policies for CHI initiating visits also apply to CHI services furnished by CSWs, MFTs, and MHCs. Please see the 2024 PFS final rule (88 FR 78921 through 78932) and 2025 PFS final rule (89 FR 97821 through 97824) for additional information regarding CHI services and CHI initiating visits.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters generally supported our proposal to allow for CPT code 90791 (Psychiatric diagnostic evaluation) or the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 (and any subsequent HBAI codes) to serve as initiating visits for CHI, as this proposal allows behavioral health practitioners to conduct critical initiating assessments for CHI, leveraging their training in behavioral health, psychosocial evaluation, and patient navigation. The commenters stated that these initiating visits are well-matched to the training of non-physician mental health practitioners and may encourage stronger care coordination, earlier intervention, and improved patient experience through improved access and efficiency. The commenters requested that we allow all psychotherapy services to serve as initiating visits for CHI (for example, CPT codes 90791-90853).

Response: We appreciate commenters for their support for our proposal. Also, we appreciate the additional suggestions and information regarding the inclusion of all psychotherapy services as CHI initiating visits, however, we continue to believe that CPT code 90791 (Psychiatric diagnostic evaluation) and the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 are most analogous to E/M services.

After consideration of public comments, we are finalizing our proposal to allow CPT code 90791 (Psychiatric diagnostic evaluation) or the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 (and any subsequent HBAI codes) to serve as initiating visits for CHI.

4. Technical Refinements to Revise Terminology for Services Related to Upstream Drivers of Health

a. Policies to Improve Care for Chronic Illness and Behavioral Health Needs

(1) Social Determinants of Health Risk Assessment (HCPCS code G0136)

In the CY 2024 PFS final rule (88 FR 78932 through 78937), we finalized coding and payment for HCPCS code G0136 (*Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5 to 15 minutes, not more often than every 6 months*). After further review of utilization information, we stated in the proposed rule that we had come to believe that the resource costs described by HCPCS code G0136 are already accounted for in existing codes, including but not limited to E/M visits. Therefore, we proposed deleting this code for CY 2026. Accordingly, we proposed to remove this code from the Medicare Telehealth Services list.

Additionally, we proposed conforming regulation text updates at 42 CFR 410.15. We proposed to revise § 410.15(a) as follows: in paragraph (a), by revising the definition of First annual wellness visit providing personalized prevention plan services by removing paragraph (xiii) and redesignating paragraph (xiv) as (xiii); and, in revising the definition of Subsequent annual wellness visit providing personalized prevention plan services by removing paragraph (xi) and redesignating paragraph (xii) as (xi).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters did not support our proposal to delete HCPCS code G0136. Commenters identified that this service may have low utilization since it is still fairly new, and increased uptake for codes often takes a few years. The commenters stated that early low utilization is not evidence of lack of value, but rather, may reflect a more typical billing pattern for a new code.

The commenters did not agree that associated resource costs are accounted for in existing codes, including but not limited to E/M visits. The commenters stated that E/M services focus only on the known needs of patients and that the SDOH risk assessment is a time-consuming service that often prompts many questions and discussions that exceed the scope of a routine office visit. Commenters stated that the time and resources involved in a SDOH risk assessment are separate from the services performed as part of E/M visits. Commenters cited that 25 percent or more of primary care activities may already go without reimbursement, and this would be adding additional activities to those that are not reimbursed. The commenters stated that removing reimbursement for this work and assuming the work of HCPCS

code G0136 occurs in an E/M visit undervalues the work of whole-person care and places the most vulnerable beneficiaries at risk.

Some commenters believe that the deletion of HCPCS code G0136 would result in practitioners no longer providing this service if CMS payment is no longer made. Commenters stated that this could result in providers being unaware of barriers to care, resulting in medical care, care plans, and patient outcomes being hindered with little understanding of the cause. The commenters were also concerned about the continuity of data from patients who have received the SDOH risk assessment in the past and may need a follow-up assessment, noting this would not allow data comparisons over time to be accurate and valid. The commenters believe that the deletion of this code may negatively impact patient care, since many patients do not report every relevant symptom or SDOH risk factor without first being prompted by a physician. They stated that this may be due to patients feeling reluctant, fearful, and distrustful about disclosing the risks they face, whereas the SDOH risk assessment may mitigate these factors.

The commenters additionally noted that elements of SDOH risk assessment may align with the Administration's efforts to combat chronic disease. Many commenters cited HCPCS code G0136 as a tool used for supporting the prevention and management of chronic disease in response to the RFI on improving care for chronic illness in the CY 2026 PFS proposed rule. The commenters also believe that the removal of this code may hinder efforts to address the root causes of chronic illness and recognize the comprehensive approach required for holistic health care. The commenters believe the removal of this service may make prevention and treatment of chronic disease more difficult, as health behaviors and social determinants of health are inextricably intertwined. The commenters also stated that HCPCS code G0136 assists in the identification of environmental impacts, which may allow for early interventions that prevent or mitigate chronic disease.

The commenters stated that the removal of this code may result in increased costs to the Medicare Trust Fund, noting their review of evaluation findings for a previous CMS Innovation Center model, Accountable Health Communities (AHC), which integrated a social determinants of health risk assessment and which showed an 8 percent reduction in emergency department visits for patients on Traditional Medicare, as well as demonstrating lower total expenditures and fewer inpatient admissions and unplanned readmissions (for conditions like uncontrolled diabetes or hypertension). We are

summarizing commenters' discussion of this evidence, which indicates SDOH factors can be predictors of health outcomes, health care utilization, and cost.

The commenters stated the deletion of this code conflicts with CMS' statutory obligation to make payment for the resource costs involved in furnishing physician services. Since this is a service that physicians (and non-physician practitioners) are currently performing, commenters did not agree that CMS would meet its statutory obligation to establish payment amounts for all physician services that reflect the resources used in furnishing the service if the code were deleted. The commenters stated that CMS removing payment for this service would result in practitioners no longer providing this service, which may negatively impact chronic disease treatment. The commenters believe that by identifying high-risk patients and conducting risk assessments under HCPCS code G0136, practitioners can prioritize and streamline assessments, resulting in less waste.

Some commenters who did not support the deletion of this service requested that, to resolve some of the issues we identified with this code in the proposed rule, we make the code a stand-alone code as opposed to an add-on code. Some commenters also suggested we recharacterize the code to align with the Administration's efforts to address the root causes of chronic illness.

A few commenters supported our proposal to delete this code, stating that patients' 'upstream drivers' or 'social determinants of health' are already identified via routine screening, and that the deletion of HCPCS code G0136 would alleviate the unnecessary administrative burden of capturing SDOH assessments. A few commenters also supported deleting this code, as the CPT E/M guidelines were revised in 2021 to reflect that SDOH factors can influence the level of medical decision-making when selecting the most appropriate level E/M visit.

Response: We appreciate the commenters for their feedback on our proposal to remove HCPCS code G0136. We recognize commenters wish to utilize future versions of HCPCS code G0136 to address root causes of disease. While the root causes of chronic disease are often multi-factorial and holistic, tailored interventions may be optimal, and assessing risk related to the root causes of many chronic conditions begins with assessing essential, common behaviors such as physical activity levels and nutrition (that is, diet composition). These two essential areas both support disease prevention, and improvement in these areas are the first step in chronic disease management (for example, hypertension

and diabetes). We agree with the commenters' suggestions to recharacterize the code to align with the Administration's efforts to address the root causes of chronic illness. As such, we are finalizing retaining HCPCS code G0136 and revising the code descriptor to read *"Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5-15 minutes, not more often than every 6 months."*

While there may be some overlap between the previous version of the SDOH risk assessment in that they are addressing areas relevant to an individual's health, we believe this change reflects a return to more clinically salient areas of risk assessment. Physical activity and nutrition risk assessment refers to a review of the individual's identified risk factors related to physical activity and/or nutrition that influence the diagnosis and treatment of medical conditions. Beginning in CY 2026, we are finalizing that the purpose of HCPCS code G0136 is to identify and value the work involved in the administering of a physical activity and/or nutrition risk assessment as part of a comprehensive medical history when medically reasonable and necessary in relation to the associated E/M or behavioral health visit. HCPCS code G0136 may be reasonable and necessary when used to inform the patient's diagnosis or treatment and the treatment plan established during the associated E/M or behavioral health visit. We expect that the practitioner furnishing HCPCS code G0136 would, at a minimum, refer the patient to relevant resources and take into account the results of the assessment in their medical decision-making, or diagnosis and treatment plan for the visit. Physical activity and nutrition risk assessment, through a standardized, evidence-based tool, can more effectively and consistently identify unmet physical activity and/or nutrition needs and enable comparisons across populations. The administration of a standardized, evidence-based physical activity and/or nutrition risk assessment tool must be tested and validated through research. Examples of evidence-based tools to assess nutrition include, but are not limited to, the Mini-EAT tool[95], the Starting the Conversation: Diet tool[96], and Short Dietary Assessment Instruments[97]. Examples of evidence-based tools to assess physical activity include, but are not limited to, the Physical

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[95] Lara-Breitinger, K. M., Medina Inojosa, J. R., Li, Z., Kunzova, S., Lerman, A., Kopecky, S. L., & Lopez-Jimenez, F. (2022). Validation of a brief dietary questionnaire for use in clinical practice: Mini-eat (eating assessment tool). Journal of the American Heart Association, 12(1). https://doi.org/10.1161/jaha.121.025064.
[96] Paxton, A. E., Strycker, L. A., Toobert, D. J., Ammerman, A. S., & Glasgow, R. E. (2011). Starting the conversation. *American Journal of Preventive Medicine*, *40*(1), 67–71. https://doi.org/10.1016/j.amepre.2010.10.009.
[97] EGRP/DCCPS/NCI/NIH *Short dietary assessment instruments*. Short Dietary Assessment Instruments. https://epi.grants.cancer.gov/diet/screeners/.

Activity Vital Sign tool[98], the CHAMPS Physical Activity Questionnaire for Older Adults[99], and the Rapid Assessment of Physical Activity (RAPA) or Telephone Assessment of Physical Activity (TAPA)[100]. HCPCS code G0136 is payable when both a physical activity and nutrition risk assessment are performed, or when either a physical activity or risk assessment is performed if there is a clinical scenario where only one is reasonable and necessary. For example, if a beneficiary has recently started a new diet but their physical activity levels have not been assessed, only a physical activity risk assessment may be reasonable and necessary.

All billing rules for HCPCS code G0136 will remain the same, including that in addition to an outpatient E/M visit (other than a level 1 visit by clinical staff), HCPCS code G0136 can also be furnished with CPT code 90791 (Psychiatric diagnostic evaluation) and the Health Behavior Assessment and Intervention (HBAI) services, described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168. HCPCS code G0136 also remains an optional, additional element of the Annual Wellness Visit (AWV) with an additional payment and no applicable beneficiary cost sharing.

We reiterate, as stated in the CY 2024 PFS final rule (88 FR 78936), that HCPCS code G0136, when performed in conjunction with an E/M or behavioral health visit is not intended to be a routine screening at standard intervals or every visit, but rather tied to one or more known or suspected physical activity and/or nutrition needs that may interfere with the practitioners' diagnosis or treatment of the patient. Although it is not required for the risk assessment to be performed on the same date as the associated E/M or behavioral health visit for the operational ease of practitioners, we continue to believe that in most cases, HCPCS code G0136 would not be performed in advance of the associated E/M or behavioral health visit. We are retaining the limitation on payment for HCPCS code G0136 of once every 6 months per practitioner per beneficiary.

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[98] Exercise is Medicine. Physical Activity Vital Sign Sheet. https://www.exerciseismedicine.org/wp-content/uploads/2021/04/EIM-Physical-Activity-Vital-Sign.pdf.

[99] Stewart, A. L., Mills, K. M., King, A. C., Haskell, W. L., Gillis, D., & Ritter, P. L. (2001). CHAMPS physical activity questionnaire for older adults: outcomes for interventions. *Medicine and science in sports and exercise*, *33*(7), 1126–1141. https://doi.org/10.1097/00005768-200107000-00010.

[100] University of Washington Health Promotion Research Center. (2006). *Rapid Assessment of Physical Activity (RAPA)*. https://depts.washington.edu/hprc/programs-tools/tools-guides/rapa/.

We are also retaining the current valuation for HCPCS code G0136, which is assigned a work RVU of 0.18. HCPCS code G0136 will also remain on the Medicare Telehealth Services List. We may consider information from interested parties for future rulemaking.

For Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) the payment policy for HCPCS code G0136 remains as stated in the CY 2024 PFS final rule. When the assessment, as described by HCPCS code G0136, is furnished as an optional element of the AWV, only one visit is paid, that is, it will be paid under the AIR or the lesser of charges or the PPS rate with the AWV adjustment. Beneficiary cost sharing is not applicable when this assessment is furnished as an optional element of the AWV. Consequently, when this assessment is furnished with a billable visit (other than an AWV) on the same day in an RHC, only the visit will be paid under the AIR and coinsurance and deductible will be applied. For FQHCs, this assessment is not considered a qualifying visit. When the assessment is furnished in conjunction with a qualifying visit (other than an AWV) on the same day in a FQHC, only the visit will be paid under the FQHC PPS and coinsurance will be applicable (88 FR 79073 through 79076).

(2) Community Health Integration Services (HCPCS codes G0019)

In response to the CY 2024 PFS proposed rule, we received several comments requesting that CMS revise some of the language used in the Community Health Integration (CHI) (HCPCS codes G0019) code descriptor to better fit the purpose of CHI services. Some of the examples that commenters provided as an alternative to "social determinants of health" included: "social drivers of health, drivers of health, or health-related social needs." Many of these commenters noted that other CMS programs use the term social drivers of health and requested that CMS use consistent naming conventions (88 FR 78933). After further consideration of the code descriptors, we proposed to replace the term "social determinants of health (SDOH)" with the term "upstream driver(s)". We have determined that the term "upstream driver(s)" is more comprehensive and includes a variety of factors that can impact the health of Medicare beneficiaries. The term "upstream driver(s)" encompasses a wider range of root causes of the problems that practitioners are addressing through CHI services. This type of whole-person care can better address the upstream drivers that affect patient behaviors (such as smoking, poor nutrition, low physical activity,

substance misuse, etc.) or potential dietary, behavioral, medical, and environmental drivers to lessen the impacts of the problem(s) addressed in the initiating visit.

We proposed the following changes to HCPCS codes G0019, and proposed conforming revisions to codes describing similar services to reflect the updated terminology, including services furnished by RHCs, FQHCs, and OTPs.

G0019—Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address upstream driver(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the upstream driver(s) and the problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services to address upstream driver(s).*

Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the upstream driver(s), and educating the patient on how to best participate in medical decision-making.

- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the upstream driver(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation.*

++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the upstream driver(s), and adjust daily routines to better meet* diagnosis *and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals*.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed that the term "upstream drivers" encompasses a wider range of root causes of the problems that practitioners are addressing through CHI services, such as potential dietary, behavioral, medical, and environmental drivers to lessen the impacts of the problem(s) addressed in the initiating visit.

Other commenters did not support our proposal, as the term "upstream drivers" is not as widely used in healthcare or coding contexts as the terms "social determinants of health" or "social drivers of health." The commenters thought that this language change may create ambiguity or disruption in documentation, billing, data collection, reporting, and care planning. Some commenters stated that current literature on the term "upstream drivers" describes approaches or interventions to improve patient health

that may be impacted by social determinants of health and does not generally include patient behaviors. Other commenters were concerned that this language change could result in emphasis being placed on individual behavioral change, without sufficient attention to social, economic, and structural barriers that prevent the diagnosis or treatment of illness or injury. Many commenters supported retaining the term "social determinants of health" or changing the language to "social drivers" as opposed to "upstream drivers."

Response: We appreciate commenters for their feedback. At this time, we continue to believe that the term "upstream driver(s)" is more comprehensive and includes a variety of factors that can impact the health of Medicare beneficiaries, such as smoking, poor nutrition, low physical activity, substance misuse, or potential dietary, behavioral, medical, and environmental drivers that when addressed, may lessen the impacts of the problem(s) addressed in the initiating visit.

Comment: Several commenters requested that we remove the term "E/M" from the CHI code descriptor to conform with our revisions proposed and finalized in this final rule to allow for CPT code 90791 (Psychiatric diagnostic evaluation) or the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 (and any subsequent HBAI codes) to serve as initiating visits for CHI.

Response: We appreciate the commenters' recommendation for revision. We agree that the term "E/M" should be removed when describing CHI initiating visits to align with all initiating visits.

After consideration of public comments, we are finalizing the code descriptor for HCPCS code G0019 as follows:

G0019—Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address upstream driver(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the upstream driver(s) and the problem(s) addressed in the initiating visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services to address upstream driver(s).*

Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the upstream driver(s), and educating the patient on how to best participate in medical decision-making.

- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the upstream driver(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*

- *Health care access/health system navigation.*

++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the upstream driver(s), and adjust daily routines to better meet* diagnosis *and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals*.

J. Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Other Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to "the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth" as "dental services.") That section of the statute also includes an exception to allow payment to be made for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Regulation at § 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

Fee for service (FFS) Medicare Parts A and B also make payment for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We also added several examples of clinical scenarios that are considered to meet that standard under § 411.15(i)(3) and amended that regulation to add more examples in the CY 2024 PFS final rule (88 FR 79022 through 79029) and in the CY 2025 PFS final rule (89 FR 97936 through 97945).

b. Submissions Received Through Public Submission Process

In the CY 2023 PFS final rule, we established a process whereby we accept and consider submissions from the public (the "public submission process") to assist us to identify additional dental services that are inextricably linked to, and substantially related and integral to the clinical success of,

other covered services (87 FR 69663 through 69688). We appreciate all those who submitted recommendations through this process. We received seven submissions from various organizations and individuals on or before February 10, 2025.

Most of the submissions recommended that we consider clinical scenarios involving beneficiaries with diabetes mellitus when contemplating payment under Medicare for dental services that are inextricably linked to other covered services. Four submitters had similar themes in their submissions that expressed the concern that the absence of treatment of chronic dental infections could complicate covered medical treatment for the management of diabetes-associated retinopathy and nephropathy. Two submitters were focused on their view of how important it is to improve oral health through treatment of oral infections like periodontitis and preventive dental care, as they asserted these dental services are related to the successful prevention and treatment of diabetic retinopathy. These two submitters were specifically concerned about beneficiaries who are at risk for diabetes-related retinopathy and vision loss or who have diabetes-related retinopathy and vision loss.

One submitter explained that their submission's purpose was not to nominate a new clinical scenario for consideration for CY 2026 rulemaking but instead was to provide an update on their ongoing research efforts in response to CMS' previous questions about the connection between autoimmune disease and oral health. The submitter referred to their nomination for CY 2025 rulemaking and CMS' respective request for comment which is discussed in the CY 2025 PFS proposed rule (89 FR 61760 through 61762). The letter emphasized that patients with autoimmune diseases often experience oral and dental complications, which can be exacerbated by immunosuppressive therapies. The submitter stated that they are currently analyzing Medicare claims data and commercial insurance data to demonstrate the positive impact of dental care on patients undergoing immunosuppressive treatment. They explained that they are particularly focused on investigating the relationship between regular preventive dental visits and systemic infection rates for those with Sjogren's disease.

Since CY 2023, we have discussed our commitment to review submissions we receive through the public submissions process. We have also expressed our intention to continue to engage in discussions with the public on a wide spectrum of issues relating to Medicare payment for dental services that may be inextricably linked to other covered services. For CY 2026, we did not make any proposals in response to

the submissions that we received and will take the information and recommendations submitted into consideration for the future.

While we did not have proposals or a comment solicitation, we received public comments on section II.J. of the CY 2026 PFS proposed rule (90 FR 32511 through 32512). We appreciate commenters for their comments and will take them into consideration for potential future rulemaking.

K. Payment for Skin Substitutes

A. Background

The CY 2014 Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period describes skin substitutes as ". . . a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers . . ." (78 FR 74930 through 74931). When a procedure utilizing a skin substitute product is performed, providers bill one or more Healthcare Common Procedure Coding System (HCPCS) codes to describe the preparation of the wound, the use of at least one skin substitute product, and application of the skin substitute product through suturing or various other techniques. Specifically, CPT codes 15271 through 15278 describe the application of skin substitutes to various size wounds and anatomical locations.

Recently, several novel industry practices have come to our attention, likely driving substantial and unusual increases in the number of available skin substitute products, the sales and distribution structure for these products, and the rapidity of products changing manufacturer ownership. These industry changes are causing a significant increase in spending under Medicare Part B for skin substitute products in the non-facility setting. According to Medicare claims data, Part B spending for these products rose from approximately $250 million in 2019 to over $10 billion in 2024, a nearly 40-fold increase, while the number of patients receiving these products only doubled. Increases in payment rates and launch prices for skin substitutes, especially newer products, account for the majority of observed Medicare spending increases on these products. Of note, as part of its workplan, the U.S. Department of Health and Human Services' Office of the Inspector General announced in November 2024 plans to review Medicare Part B claims for skin substitutes to identify payments that were at risk for noncompliance with Medicare requirements with an expected issue date of fiscal year 2026.[101]

We outlined our HCPCS Level II coding and payment policy objectives for skin substitutes in the CY 2023 Medicare Physician Fee Schedule (PFS) proposed rule (87 FR 46249) because we concluded it would be beneficial for interested parties to understand our priorities as we work to create a consistent approach for the suite of products we have referred to as skin substitutes. As discussed in the CY 2023

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[101] https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000894.asp.

PFS proposed rule, we have a number of objectives related to refining our Medicare policies in this area, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) employing a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material, so we can incorporate payment methodologies that are more consistent; and (4) promoting clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have requested that CMS address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the non-facility setting; however, interested parties have also indicated that further alignment of our policies across the non-facility and hospital outpatient department settings would reduce confusion.

On April 25, 2024, the Medicare Administrative Contractors (MACs) released a proposed Local Coverage Determination (LCD) to provide appropriate coverage for skin substitute grafts used for chronic non-healing diabetic foot and venous leg ulcers. The MACs issued the collaborative proposed Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD to make sure that Medicare covers, and people with Medicare have access to, skin substitute products that are supported by evidence that shows that they are reasonable and necessary for the treatment of diabetic foot and venous leg ulcers in the Medicare population and that coverage aligns with professional guidelines for appropriately managing these wounds. All of the MACs have delayed the effective date of the final LCDs for cellular and tissue-based products for wounds, or skin substitutes, in diabetic foot ulcers and venous leg ulcers, moving the implementation date across all MAC jurisdictions to January 1, 2026. For details, please see the final LCD, titled: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers at: https://www.cms.gov/medicare-coverage-database/basket/basket.aspx?loadBasketLink=Y&basketLinkId=552. We note that additional coverage determinations may apply to skin substitute products.

The Medicare statute, regulations, and manual provisions empower the Medicare program to determine if a product is reasonable and necessary for the treatment of a beneficiary's condition and safe and effective, not experimental or investigational, and appropriate and therefore eligible for coverage under Part B. (*See*, for example, section 1833(e) of the Act (42 U.S.C. 1395l(e)), section 1862(a)(1)(A) of the Act (42 U.S.C. 1395y(a)(1)(A)), 42 CFR 411.15(k)(1), 424.5(a)(6), Medicare Program Integrity Manual § 3.6.2.2, Medicare Benefit Policy Manual ch. 15, §§ 50.4.1-50.4.3, and Medicare Program Integrity Manual, ch. 13 §§ 13.5.3, 13.5.4.) Coverage is a threshold determination that must be satisfied before payment considerations arise. The inclusion of a product in this payment rule or in any payment file does not necessarily imply that a determination has been made by CMS or its contractors that it is reasonable and necessary and meets the other preconditions to Medicare coverage. Any skin substitute could not be covered if it were determined to be unreasonable or unnecessary for a particular beneficiary. Similarly, the use of short descriptors and associated FDA regulatory categories[102] may reflect current FDA regulation but are not intended to imply that FDA has determined that a product meets any specific FDA statutory or regulatory requirements. FDA's statutory and regulatory framework, including, for example, FDA's findings that a product is "safe and effective," is not controlling of Medicare's determination under its own authorities of whether a product is "reasonable and necessary" for an individual patient and meets all preconditions for Medicare coverage and payment. FDA does not make Medicare coverage or payment determinations, nor do FDA statutes and regulations govern Medicare coverage or payment determinations.

Medicare coverage and payment are also governed under separate statutory authorities and serve fundamentally different purposes. Coverage determinations under section 1862(a)(1)(A) (and related provisions) of the Act establish whether a service is reasonable and necessary while payment methodologies under section 1848 of the Act (and other applicable payment provisions) of the Act establish the amount Medicare will pay for covered physician services based on considerations such as resource similarity. CMS has determined that setting payment rates on a prospective basis is a different inquiry and exercise with a different set of considerations and that it makes sense here to consider how

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[102] The term "FDA regulatory categories" is used in this final rule when referring to the basis for CMS's payment policies but is not intended to reflect or imply that the products discussed within this final rule are characterized as such or grouped together by FDA.

FDA regulates skin substitute products as a factor in grouping those products in various categories as described later in this section.

We continue to believe that our existing payment policies are unsatisfactory, unsustainable over the long term, and rooted in historical practice established two decades ago prior to significant evolutions in medical technology and practice. After hosting a town hall[103] to provide an opportunity for public input, including discussion of potential approaches to the methodology for payment of skin substitute products, as well as reviewing several years of comments in response to CY rulemaking in 2023, 2024, and 2025 on this subject, we developed a proposal that addressed our stated objectives as well as many of the comments we have received.

B. Medicare Part B Payment for Skin Substitutes

1. Payment for Skin Substitutes When Used During a Covered Application Procedure Under the PFS in the Non-facility Setting

We have historically considered skin substitutes to be biologicals for payment purposes under Medicare Part B. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) established payment methodology for drugs and biologicals under section 1847A of the Act (42 U.S.C. 1395w-3a). Under this methodology, a vast majority of drugs and biologicals separately paid under Medicare Part B are paid at the Average Sales Price (ASP) plus six percent. Section 303(c) of the MMA, titled "Payment reform for covered outpatient drugs and biologicals," amended Title XVIII of the Act by adding new section 1847A of the Act. In part, this section established the use of the ASP to determine the payment limit for drugs and biologicals described in section 1842(o)(1)(C) of the Act (42 U.S.C. 1395u(o)(1)(C)) (that is, drugs or biologicals billed by a physician, supplier, or any other person and not paid on a cost or prospective payment basis) furnished on or after January 1, 2005. Because Medicare is currently paying for most skin substitutes as biologicals using the methodology under section 1847A of the Act, each skin substitute product receives a unique billing code (typically, a Level II HCPCS code) and payment limit.

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[103] CMS Skin Substitutes Town Hall, which was held virtually on January 18, 2023. More information regarding the CMS Skin Substitutes Town Hall such as links to recording and transcripts is available at *https://www.cms.gov/medicare/payment/fee-schedules/physician/skin-substitutes#:~:text=The%20CMS%20Skin%20Substitutes%20Town,Physician%20Fee%20Schedule%20(PFS).*

Section 401 of Division CC, Title IV of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) (CAA, 2021) amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires certain manufacturers without a Medicaid drug rebate agreement, such as certain manufacturers of skin substitutes, to report ASP data to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act (42 U.S.C. 1395rr(b)(14)(B)), including items, services, supplies, and products that are payable under Part B as a drug or biological. Because most skin substitutes are currently paid as biologicals using the methodology described in section 1847A of the Act, manufacturers of these products are currently required to report their ASP data to CMS every quarter. Prior to this, section 1927(b)(3)(A)(iii)(I) of the Act only required manufacturers with a Medicaid drug rebate agreement to report ASP data to CMS for drugs or biologicals described in section 1842(o)(1)(C) of the Act.

Section 1847A of the Act also includes several relevant definitions. While the definition of "single-source drug or biological" provided at section 1847A(c)(6)(D) includes "a biological," sections 1847A(c)(6)(H) and (I) of the Act offer more insight into the meaning of the term for purposes of this section. Subparagraph (I) of such section defines the term "reference biological product" as a biological product licensed under section 351 of the PHS Act (42 U.S.C. 262). Subparagraph (H) of section 1847A(c)(6) defines the term "biosimilar biological product" as "a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act."

Section 1927 of the Act (42 U.S.C. 1396r–8), which is referred to multiple times in section 1847A of the Act, also references section 351 of the PHS Act when referencing biologicals. The title of section 303 of the MMA, which added section 1847A to the Act, refers to "covered outpatient drugs," defined in section 1927(k)(2) of the Act. Subparagraph (B) of section 1927(k)(2) adds biological products to this definition when those products are licensed under section 351 of the PHS Act, among other requirements.

In the CY 2022 PFS final rule, to address the need to establish a payment mechanism for synthetic skin substitutes in the physician office setting and to be responsive to feedback received from commenters, we finalized an approach for payment of each synthetic skin substitute for which we had

received a HCPCS Level II coding application. We finalized that those products would be payable in the physician office setting and billed separately from the procedure to apply them using HCPCS A-codes (86 FR 65120).

2. Payment for Skin Substitutes Under the Outpatient Prospective Payment System (OPPS)

Prior to CY 2014, all products considered to be skin substitutes were separately paid under the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931). In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products furnished in the hospital outpatient setting into their associated application procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among Ambulatory Payment Classification (APC) assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high-cost group are described by CPT codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Claims billed with primary CPT codes 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high-cost group, and claims billed with primary HCPCS codes C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low-cost group (78 FR 74935). The graft skin substitute administration add-on codes, which include “each additional 25 sq cm” in the description (that is, CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278), are packaged into the payment rates for the primary administration codes.

For CY 2025, each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS

codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2025, the payment rate for APC 5053 (Level 3 Skin Procedures) is $612.13, the payment rate for APC 5054 (Level 4 Skin Procedures) is $1,829.23, and the payment rate for APC 5055 (Level 5 Skin Procedures) is $3,660.97. Table A-K1 lists the APC assignments and CY 2025 payment rates for the HCPCS codes describing the skin substitute application procedures. This information is also available in Addenda A and B of the CY 2025 final OPPS/ASC rule with comment period (the Addenda A and B are available on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

TABLE A-K1: CY 2025 APC ASSIGNMENTS FOR SKIN SUBSTITUTE APPLICATION HCPCS CODES

APC	APC Title	HCPCS Codes	Final CY 2025 OPPS Payment Rate
APC 5053	Level 3 Skin Procedures	C5271, C5275, C5277	$612.13
APC 5054	Level 4 Skin Procedures	C5273, CPT codes 15271, 15275, 15277	$1,829.23
APC 5055	Level 5 Skin Procedures	CPT code 15273	$3,660.97

Beginning in CY 2016, we adopted a policy where we determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC), which is calculated as the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days, exceeding the PDC threshold. We assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high-cost group. We assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976). We also assign skin substitutes with pass-through payment status to the high-cost category.

We assign skin substitutes with some pricing information but without claims data for which to calculate a geometric MUC or PDC to either the high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we use the wholesale acquisition cost (WAC) plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we use 95 percent of the average wholesale price (AWP) to assign a skin substitute to either the high-cost or low-cost category.

In the CY 2021 OPPS/ASC final rule with comment period, after the first entirely synthetic skin substitute products were introduced into the market, we revised our description of skin substitutes to include both biological and synthetic products (85 FR 86064 through 86067). Any skin substitute product that is assigned to a code in the HCPCS A2XXX series is assigned to the high-cost skin substitute group, including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series are assigned to the low-cost category until pricing information is available to compare to the MUC and PDC thresholds (89 FR 94247).

In the CY 2014 OPPS/ASC final rule, we also noted that several skin substitute products are applied as either liquids or powders per milliliter or per milligram and are employed in procedures outside of CPT codes 15271 through 15278. We stated that these products ". . . will be packaged into the surgical procedure in which they are used." (78 FR 74930 through 74931).

We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that, under the OPPS, these items cannot be assigned to either the high-cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 (85 FR 86066).

C. Current FDA Regulation of Products CMS Considers to be Skin Substitutes

The FDA regulates products that CMS considers to be skin substitutes based on a variety of factors, including product composition, mode of action, and intended use. Relevant categories of FDA regulation for skin substitute products include the following:

1. Self-determination Under Section 361 of the PHS Act and the Regulations in 21 CFR 1271 (361 HCT/Ps)

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) are defined in 21 CFR 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples include bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. Pursuant to section 361 of the Public Health Service (PHS) Act, FDA promulgated regulations at 21 CFR 1271, *et seq* that create an electronic registration and listing system for

establishments that manufacture HCT/Ps, regulate donor eligibility, and establish current good tissue practice and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps.

A subset of HCT/Ps are those that are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271 (361 HCT/Ps). The FDA has taken a risk-based, tiered approach in regulating HCT/Ps; as the potential risk posed by a product increases, so too does the level of oversight (63 FR 26745). Although FDA is authorized to apply applicable requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or the PHS Act to those products that meet the definition of drug, biological product, or device, under a tiered, risk-based approach, HCT/Ps that meet specific criteria or fall within detailed exceptions do not require premarket review and approval. HCT/Ps that do not meet all the criteria in 21 CFR 1271.10(a) are not regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. Unless an exception in 21 CFR 1271.15 applies, such products are regulated as drugs, devices, and/or biological products under the FD&C Act and/or the PHS Act and are subject to additional regulation, including applicable premarket review and approval. An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria (21 CFR 1271.10(a)):

- The HCT/P is minimally manipulated.
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P.
- Either:

++ The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

++ The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function; and

--- Is for autologous use;

--- Is for allogeneic use in a first-degree or second-degree blood relative; or

--- Is for reproductive use.

Establishments that manufacture 361 HCT/Ps, as defined by 21 CFR 1271.3(e), must register and list their 361 HCT/Ps in the FDA's electronic Human Cell and Tissue Establishment Registration System (eHCTERS), but premarket review and approval by FDA is not needed. However, FDA acceptance of an establishment registration and 361 HCT/P listing form does not constitute a determination that an establishment is compliant with applicable FDA rules and regulations, that the FDA has agreed with the manufacturer's self-determination as a 361 HCT/P, or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)). When this final rule refers to 361 HCT/Ps, it generally refers to products where an establishment has self-determined that their product is a 361 HCT/P.[104] If an HCT/P does not meet the criteria set out in 21 CFR 1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions in 21 CFR 1271.15, the HCT/P will be regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act (42 U.S.C. 262), and applicable regulations, including 21 CFR Part 1271, and premarket review generally is required.

2. 510(k) Premarket Notification Submissions, Premarket Approval Applications, and De Novo Requests

"Devices," as defined under 21 U.S.C. 321(h)(1), do not achieve their primary intended purposes through chemical action and are not dependent upon being metabolized for the achievement of their primary intended purposes. Devices may be subject to premarket review through: (1) a 510(k) premarket notification submission (510(k)) in accordance with section 510(k) of the FD&C Act and implementing regulations in subpart E of 21 CFR part 807; (2) a premarket approval application (PMA) under section 515 of the FD&C Act and regulations in 21 CFR part 814; or, potentially, (3) a De Novo classification request (De Novo request) under section 513(f)(2) of the FD&C Act and regulations in subpart D of 21 CFR part 860. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (sections 510(k) and 513(i) of the FD&C Act). Premarket approval is the most rigorous type of review

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[104] We note that establishments may seek feedback from FDA regarding their self-determination analysis and conclusion that a particular product is a 361 HCT/P. See, For example., https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group.

and generally is required for class III medical devices. Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act). De Novo classification is a marketing pathway for novel medical devices for which general controls alone (class I), or general and special controls (class II), provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Devices that are classified into class I or class II through a De Novo request may be marketed and used as predicates for future premarket notification (that is, 510(k)) submissions, when applicable.

3. Biologics License Application

To lawfully introduce or deliver for introduction into interstate commerce a drug that is a biological product, a valid biologics license application (BLA) must be in effect under section 351(a)(1) of the PHS Act, 42 U.S.C. 262(a)(1), unless exempted under 42 U.S.C. 262(a)(3). Such licenses are issued only after showing that the product is safe, pure, and potent. Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products (21 CFR 601.2(d)). Potency has long been interpreted to include effectiveness (21 CFR 600.3(s)).

The definition of the term "biological product" in section 351(i) of the PHS Act is: "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." (42 U.S.C. 262(i)). In contrast to the registration and listing requirements for a 361 HCT/P or the substantial equivalence requirements for 510(k)s, products licensed under section 351 of the PHS Act are required to meet stringent pre-and post-market requirements to ensure the products' safety and efficacy when marketed. Table A-K2 lists several other notable differences between the relevant FDA regulatory categories for products CMS considers to be skin substitutes.

TABLE A-K2: COMPARISON OF FDA CLASSIFICATIONS

Classification	Review Goal Within	FY2025 Standard Application Fee
361 HCT/P	N/A[105] (registration required)	N/A
510(k)[106]	90 Days	$24,335
PMA	180 or 320 days[107]	$540,783
BLA (original application for products requiring clinical data)	10 months[108]	$4,310,002[109]

D. *Payment of kin Substitute Products under the PFS and OPPS*

1. Payment for Skin Substitute Products as Incident-To Supplies

We have carefully considered our policy objectives, which include: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) employing a uniform approach across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material; and (4) providing clarity for interested parties on CMS skin substitutes policies and procedures. We proposed, starting January 1, 2026, to separately pay for the provision of certain groups of skin substitute products as incident-to supplies when, for those products that are coverable under Medicare's rules, they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. This proposal does not apply to biological products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act. While we considered proposing to pay separately for skin substitutes initially under just the PFS in non-facility settings consistent with current practice, one of our primary policy objectives is to ensure a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; and so, we ultimately determined that the suite of products referred to as skin substitutes should be treated in a uniform manner across different outpatient care settings, to the extent permitted by applicable law. The physician, in consultation with his or her patient, decides the site of

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[105] No premarket authorization is required for 361 HCT/Ps.
[106] https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.
[107] These numbers include either a review within 180 days for decisions without advisory committee input or a review within 320 days for decisions with advisory committee input, respectively.
[108] PDUFA performance goals call for FDA to review and act on 90 percent of original BLA submissions within 10 months of the 60-day filing date. Other regulatory pathways may have different timelines. See https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review; https://www.fda.gov/drugs/development-approval-process-drugs.
[109] https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.

service for treatment. While many factors are considered as a part of that decision, substantial differences in payment for the application of the same skin substitute product in one site of service versus another, or between similar skin substitute products, should not be one of them. Establishing a consistent framework for how these products are treated within the non-facility and hospital outpatient settings would empower providers to make the best treatment decisions for their patients, ensure equitable access to needed services, and pay appropriately for these services. We also considered bundling payment for skin substitute products in both the PFS and OPPS as part of this proposal. While supplies are generally bundled into the payment of the service in both the physician office and hospital outpatient departments, for many years skin substitute products have been paid separately in the physician office setting, where the majority of these products are currently applied. So, we have determined that bundling payment for skin substitute products with their administration procedures across both settings under this new proposal, before efforts are made to address improper utilization patterns, would be premature. Depending on the outcomes of this final policy, we may consider packaging skin substitute products with the related application procedures in both the hospital outpatient setting and non-facility setting in future rulemaking. We solicited comments on our proposal to separately pay for the provision of certain groups of skin substitute products as well as on our proposal to implement this policy in both the non-facility and hospital outpatient settings. For additional details on the OPPS proposal for skin substitutes, please see the CY 2026 OPPS/ASC proposed rule with comment period; the remainder of this policy proposal will focus on implementation under the PFS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' goal of aligning payment and coding policies across different sites of care. They agree that a consistent, site-neutral payment system empowers providers to choose the most clinically appropriate setting based on patient needs rather than financial incentives. Commenters noted this would reduce the confusion, administrative burden, and disparities in care caused by the current system. They see this policy as a way to establish a fair and uniform standard that centers treatment decisions around the patient.

Many commenters also supported CMS' proposal to pay for skin substitutes separately from the application procedure. Several stated that these products are separately reimbursable and add significant clinical value. They noted that separate payment ensures consistent treatment availability, preserves access for patients, and avoids disincentives for treating larger wounds. Several commenters expressed appreciation that CMS did not move forward with a previous proposal to bundle the products, which they believe would have harmed patients with large wounds. They regarded the proposed policy as a more clinically and operationally sound approach.

Several commenters specifically supported discontinuing the bundling of skin substitute payments in the Hospital Outpatient Department (HOPD) and Ambulatory Surgical Center (ASC) settings. The commenters suggested the current system, which bundles payment in the HOPD but pays separately in the office, has created a disincentive to treat larger wounds in facilities, pushing those cases disproportionately into the physician's office or even more expensive inpatient settings. They applauded the per-square-centimeter methodology for aligning payment with wound size and expanding access across all sites.

Response: We appreciate the commenters for their support.

Comment: Other commenters opposed the move away from bundled payments. MedPAC, for example, did not support unbundling skin substitutes in the facility setting, stating that paying for items separately undermines payment bundles, can lead to overuse, and shifts financial burden from providers to Medicare and its beneficiaries. Another commenter supported maintaining a bundled approach to align with longstanding policy and statutory authority.

Several commenters recommended that CMS delay any changes to the HOPD payment methodology. They suggested that CMS should first assess the impact of the payment reforms in the non-facility setting before applying them to the hospital outpatient setting to avoid unintended consequences, such as shifting care to more expensive settings.

Response: While we acknowledge the concerns about unbundling raised by commenters, ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings has been a long-stated policy objective. As noted previously in this section, we have determined that bundling payment for skin substitute products with their administration

procedures across both settings under this new proposal, before efforts are made to address improper utilization patterns, would be premature. Depending on the outcomes of this policy, we may consider packaging skin substitute products with the related application procedures in both the hospital outpatient setting and non-facility setting in future rulemaking.

Comment: Many commenters warned that the proposed payment rate for the application codes create a new, major disparity between care settings. They pointed out the large gap between the proposed physician application payment rate of ~$150 in an office/mobile setting and the combined facility and physician facility setting payment rates of over $800 in an HOPD. They stated this disparity will create a strong financial incentive to shift patient care to the more expensive HOPD setting, which could strain hospital capacity, create access issues for rural and underserved patients, and cause physician offices and mobile practices to shutter. Several commenters highlighted the unique challenges and higher costs faced by providers serving rural and homebound patients. They recommended CMS offer financial incentives, enhance telemedicine reimbursement, and provide add-on payments or grants to ensure these vulnerable populations do not lose access to care. To achieve true site neutrality, they strongly suggested CMS increase the application fee for clinicians in non-facility settings to close this gap.

Other commenters supported the proposed RVUs and payment rates for the application procedure codes in both the HOPD and MPFS settings, finding them to be a fair assessment of clinical resource utilization.

Another commenter stated that CMS should increase the proposed APC payment rates for these procedures in the HOPD setting, as the proposal demotes some codes to lower-paying APCs, which exacerbates existing disincentives for treating wounds in the hospital.

Response: We acknowledge the disparities in the payment rates for the application codes between settings. As described in section II.B. of this final rule, we are open to exploring alternative data sources, including use of OPPS cost data, to inform PFS rate setting for certain services. We also recognize the possibility raised by interested parties that some of the excessive payment for the skin substitute products may have been useful in subsidizing costs associated with providing these services in beneficiaries' homes. We look forward to continued dialogue on this point as well as on the point of access to care for homebound and other beneficiaries for whom care is reasonable and necessary.

After careful consideration of the comments, we are finalizing our proposal to pay separately for the provision of certain groups of skin substitute products as well as our proposal to implement this policy in both the non-facility and hospital outpatient settings as proposed.

We proposed, under the PFS, to pay separately for the use of specific skin substitute products (that is, skin substitute products that are not regulated as biological products under section 351 of the PHS Act) that are eligible for Medicare coverage during a covered application procedure in the non-facility setting as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act. Supplies are a large category of items that typically are either for single use or have a shorter use life span than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in outpatient settings, including certain implantable medical devices. “Incident-to supplies” refers to supplies that are furnished as an integral, although incidental, part of the physician’s professional services in the course of diagnosis or treatment of an injury or illness, among other requirements at 42 CFR 410.26(b). Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through 15278, and the procedure of treating the wound and applying a covering to the wound is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures. We sought comments on our proposal to separately pay for provision of skin substitutes as incident-to supplies under the PFS in the non-facility setting.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters opposed reclassifying skin substitutes, particularly amniotic and placental-derived products, as supplies. The commenters stated this classification is a misstep that diminishes the products' clinical value, calling the products advanced, life-changing biologic therapies, not simple bandages or dressings. Some stated CMS lacks legal authority, as skin substitutes do not meet the statutory definition of an "incident-to supply." They stated the reclassification is legally, clinically, and definitionally incorrect, as these products are the primary intervention, not an incidental part of a service, and interact directly with body tissues.

Response: Section 1861(s)(2)(A) of the Act defines "medical and other health services" as services and supplies furnished incident to a physician's professional service that are commonly furnished in physicians' offices and provided either without charge or as part of a physician's bill. As stated previously in this section, supplies are a large category of items that typically are either for single use or have a shorter use life span than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in outpatient settings, including certain implantable medical devices, including class III medical devices requiring premarket approval, which is the most rigorous review required of a skin substitute that is also a medical device. "Incident-to supplies" refers to supplies that are furnished as an integral part of the physician's professional services in the course of diagnosis or treatment of an injury or illness, among other requirements at 42 CFR 410.26(b). Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through 15278, and the procedure of treating the wound and applying a covering to the wound is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures.

Comment: Many commenters supported the reclassification of non-BLA skin substitutes as incident-to supplies. They see it as an essential, overdue, and rational approach to realign incentives away from overuse and toward more clinically appropriate care. They stated that this change is expected to curb the significant fraud, waste, and abuse that has plagued the current system.

Response: We appreciate the commenters for their feedback on our proposal to treat and pay for all covered skin substitute products as incident-to supplies. CMS agrees that this proposal will help to resolve issues such as exorbitant price increases and curb fraud, waste, and abuse.

Comment: Several major physician groups expressed concerns that paying for these high-cost supplies within the PFS relative value system would have a devastating impact on payments for all other physician services. These commenters argue that due to PFS budget neutrality, introducing billions of dollars in supply costs into the practice expense (PE) pool would distort relativity and inevitably trigger across-the-board reduction in RVUs for other services. Many commenters stated that even if unit costs decrease under the new pricing methodology, the overall magnitude of aggregate spending means inclusion in the PFS relative value system could have long-term consequences for payment adequacy of

other unrelated services. These groups strongly suggested CMS to create a separate payment mechanism outside of the PFS relative value system to avoid this instability, similar to payment for Part B drugs.

Response:

We recognize the significance of reclassifying these products as incident-to supplies under the PFS, especially considering the dramatic increases in spending on this category of products in recent years. However, we disagree that this change is inappropriate since, as previously articulated, we maintain that these products are more appropriately categorized as incident-to supplies rather than as drugs and biologicals. We also acknowledge the longstanding concerns many commenters have noted regarding the inclusion of disposable supplies, especially those with high costs, as part of payment under the PFS, especially relevant for PFS budget neutrality and relativity. However, we do not believe it would be consistent with current statutory authority for such concerns to drive the appropriate classification of particular kinds of products.

We would also point out that the PFS budget neutrality, as implemented on an annual basis consistent with the statute, adjusts RVUs to account for changes in pricing and coding, not overall changes in volume between years. Consequently, the assigning of codes describing the provision of these products' PE RVUs does not have a direct, initial impact on the calculation of other PE RVUs. Instead, the future changes in rates for these services will be incorporated into PFS relativity and budget neutrality once data become available. By grouping these products for payment purposes, we expect that market competition will likely result in lowering prices for most skin substitutes products. For example, once data becomes available for CY 2027 and is incorporated into PFS ratesetting, overall reductions in payment amounts for skin substitutes could have a positive result on PFS relativity and budget neutrality for other services paid under the PFS by CY 2028.

After careful consideration of the comments, we are finalizing our proposal to pay separately for the provision of skin substitutes as incident-to supplies under the PFS in the non-facility setting as proposed.

Skin substitutes have historically been paid separately in the non-facility setting as biologicals instead of supplies when used during a covered application procedure. Products CMS considers to be skin substitutes may also meet FDA's definition of a biological product, either directly or as an analogous

product. However, section 1847A of the Act, which includes the controlling provisions for setting Medicare payment for drugs and biologicals billed by a physician, generally refers to biologicals in ways that do not encompass most skin substitutes. While most skin substitutes are either medical devices regulated under the FD&C Act or products regulated solely under section 361 of the PHS Act, subparagraphs (H) and (I) of section 1847A(c)(6) of the Act only refer to biological products under section 351 of the PHS Act. Section 1847A of the Act also references section 1927 of the Act, which again refers to section 351 of the PHS Act when referencing biologicals. In addition, to operationalize the payment system, section 1847A of the Act includes extensive references to National Drug Codes, a type of drug identifier published by the FDA and generally not assigned to most skin substitutes, which further supports our proposal to stop utilizing 1847A payment methodologies for skin substitutes that are not licensed under section 351 of the PHS Act. For example, section 1847A(b)(4)(A) of the Act directs uses of the lesser of the average sales price or wholesale acquisition cost when determining the payment amount for a single-source drug or biological for all National Drug Codes assigned to the drug or biological. The methodology for calculating the volume-weighted average sales price is described in paragraph (6) of section 1847A(b) of the Act, which describes a process that again specifies the use of National Drug Codes. Because skin substitutes generally do not have National Drug Codes, CMS has operationalized this process for skin substitutes by allowing manufacturers of skin substitutes to self-select an Alternate ID to distinguish between different skin substitute products.[110] However, the use of an alternative identification method is not required by the statute, and the calculation of a payment limit under section 1847A of the Act for these products is otherwise not possible.

We note that section 351 and section 361 of the PHS Act are two distinct regulatory frameworks. Section 351 biological products must seek FDA pre-marketing approval (using clinical studies that are required by the applicable section 351 regulations) and are applicable to the prevention, treatment, or cure of a disease or condition. In contrast to the prerequisites for marketing products that fall under section 351 of the PHS Act, no FDA approval or clearance is required for marketing the self-determined 361 HCT/Ps. Section 361 products also do not receive an FDA license of approval for a specific prevention, treatment, or cure of a disease or condition and do not require controlled clinical trials to demonstrate effectiveness

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[110] https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.

prior to marketing. The self-determined 361 HCT/Ps are also self-determined to be limited to intended uses that reflect homologous use for that particular product.

In light of our careful review of the applicable statutory provisions governing skin substitute products paid under the ASP methodology under 1847A of the Act, the FDA's regulatory frameworks used for these products, and the skyrocketing increase in Medicare spending for such products, we proposed to pay separately for skin substitute products (other than products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act) that are eligible for Medicare coverage during a covered application procedure in the non-facility setting as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act.

One purpose of the new policy is to limit some of the current profiteering practices occurring in this industry. For example, as reflected in the last several years of CMS' ASP pricing files, we have observed a dramatic increase in launch prices. It is unclear how these prices could be attached to realistic changes in resource costs as many of these new products are allegedly minimally manipulated tissues. Our policy is likely to disincentivize this practice, as well as several other novel industry practices that have come to our attention by preventing exploitation of skin substitute pricing under section 1847A of the Act, overuse of expensive skin substitute products, and waste resulting from use of more-expensive skin substitute products over clinically appropriate, less-expensive alternatives. Notably, there has not been significant growth in payments for skin substitutes in the OPPS, which unconditionally packages the payment for skin substitute products with their associated application procedures. We note that the relevant statutory provisions, when considered together, do not require all of these kinds of products to be paid as biologicals under section 1847A of the Act. Therefore, under this policy, unless a skin substitute is approved as a drug or as a biological product under section 351 of the PHS Act, in which case we would continue to pay for it consistent with section 1847A of the Act, we would consider it an incident-to supply for payment purposes under the PFS with the definitions and rates described below. For Medicare purposes, we proposed to codify the definition of "biological" as "a product licensed under section 351 of the Public Health Service Act" at §§ 414.802 and 414.902. We sought comments on our proposal to limit the application of section 1847A of the Act to skin substitutes that are approved as a drug or as a biological product under section 351 of the PHS Act and our proposed edits to the regulations.

We received divided comments on our proposal to codify the definition of “biological” in regulation. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that CMS' proposal to narrow the definition of "biological" to only include products licensed under section 351 of the PHS Act is a misapplication of the law and conflicts with the Act. They contend that the Act itself provides a broader definition in section 1861(t)(1) of the Act, which includes products listed in the U.S. Pharmacopoeia (USP) or approved by hospital P&T committees, a definition that many skin substitutes meet, including section 361 products. Commenters state that if Congress had intended to limit the term "biological" to section 351 products in the payment statute (Section 1847A of the Act), it would have done so explicitly, as it has in other parts of the law. Furthermore, they noted that the Consolidated Appropriations Act of 2021 referred to these products as "drugs and biologicals," signaling that Congress considers them as such for payment purposes. The commenters stated that for decades CMS has appropriately classified and paid for skin substitutes as drugs or biologicals under section 1847A of the Act. They stated that the proposal to abruptly reclassify them is an unexplained reversal of this long-standing policy and is therefore "arbitrary and capricious."

Response: Section 1861(t)(1) of the Act states, in relevant part, that the term “drugs” and the term “biologicals” include only products that are included (or approved for inclusion) in the (USP), the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or certain products listed in the Accepted Dental Remedies, or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital; subparagraph (t)(2) adds that the term “drugs” includes any drugs or biologicals used in certain anticancer chemotherapeutic regimens in the definition. The definition of these terms does not include certain medical supplies. Reliance on this provision to determine that a skin substitute is a biological payable under section 1847A of the Act is problematic for several reasons. To begin, we note that this provision does not require that *all* products included in the listed compendia are deemed drugs and biologicals. Instead, it states that “drugs” and “biologicals” include *only* such drugs and biologicals as are included in the compendia. Second, only one of the listed compendia in section 1861(t)(1) of the Act that is still in publication: a combination compendium containing USP and the National Formulary (USP-NF), which contains standards for medicines, dosage

forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics.[111] The compendia issued a statement in 2018 that it would no longer develop new monographs for biologics unless there is consensus from interested parties supporting its creation, including the support of FDA.[112] As a result, very few of CMS's paid biologicals actually have product-specific monographs in that compendium. Instead of product-specific monographs, the USP primarily develops performance standards and general guidelines to support the quality assessment of biologics. This is also true in the case of skin substitutes. References to these types of products in the USP are not product-specific monographs. Instead, these references are general descriptions of product types. As the source and manufacture of products with biological activity can dramatically change their safety and efficacy, these general references are not sufficient to describe any product with specificity. Therefore, CMS relies on the language in section 1847A of the Act to authorize payment for products described therein.

The Consolidated Appropriations Act, 2021, Pub. Law 116–260, division CC, section 401(c), amended section 1847A(f)(A) to state that, manufacturers of drug or biological including items, services, supplies, and products that are payable under Medicare Part B as a drug or biological that have not entered into a National Medicaid Drug Rebate Agreement are required to report ASP (and WAC) data to CMS. Under this policy, as finalized, skin substitute products (other than those approved via BLA under section 351 of the PHS Act) will no longer be payable as drugs or biologicals under Medicare Part B and will no longer be required to report ASP data to CMS.

Finally, as noted previously, we outlined our HCPCS Level II coding and payment policy objectives for skin substitutes in the CY 2023 PFS proposed rule (87 FR 46249) and stated we believed that our existing payment policies were unsatisfactory, unsustainable over the long term, and rooted in historical practice established two decades ago prior to significant evolutions in medical technology and practice. CMS also hosted a town hall[113] to provide an opportunity for public input, including discussion of potential approaches to the methodology for payment of skin substitute products, and reviewed several

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[111] https://www.uspnf.com/purchase-usp-nf

[112] https://www.usp.org/news/statement-on-monographs-for-biologics#:~:text=Rockville%2C%20MD%20%E2%80%93%20April%202%2C,About%20USP.

[113] CMS Skin Substitutes Town Hall, which was held virtually on January 18, 2023. More information regarding the CMS Skin Substitutes Town Hall such as links to recording and transcripts is available at *https://www.cms.gov/medicare/payment/fee-schedules/physician/skin-substitutes#:~:text=The%20CMS%20Skin%20Substitutes%20Town,Physician%20Fee%20Schedule%20(PFS).*

years of comments in response to CY rules in 2023, 2024, and 2025 on this subject before developing this proposal to address our stated objectives.

Comment: Other commenters agreed with CMS' interpretation. The commenters supported the proposal to reserve payment methodology under section 1847A of the Act for products that have undergone the rigorous FDA Biologics License Application (BLA) process under section 351 and agreed that non-BLA products do not meet the statutory definition of biologicals contemplated for payment under section 1847A of the Act, making the "incident-to supply" classification a rational approach. They believe this accurately reflects the statutory definition of a biological and rightly rewards manufacturers who invest in the highest level of regulatory review. Other commenters requested that CMS clarify that skin substitute products do not fall under the discarded drug or inflation rebate policies.

Response: We appreciate the commenters for their support. We clarify that skin substitute products that are not regulated as drugs or biological products under section 351 of the PHS Act and that are paid as incident to supplies are not subject to the Medicare discarded drug policy. At this time, skin substitutes are excluded from Part B inflation rebates as described at § 427.101(b)(5) and as finalized in the CY 2025 PFS final rule (89 FR 98235).

Comment: A commenter warned that continuing to pay for the few BLA-approved products under section 1847A of the Act while moving all others to a flat rate would create a perverse incentive for those manufacturers to continue increasing prices.

Response: As previously described, we believe that the payment methodology described in section 1847A of the Act applies to drugs and biological products approved under a BLA when they are provided in the non-facility setting. Further, such licenses are issued only after showing that the product is safe, pure, and potent and may justify a higher payment rate. Finally, between the longer time required to bring these products to market, potential rebate requirements, and the changes to ASP reporting described in section XX of this final rule, we believe opportunities for dramatic pricing increases will be significantly curtailed. However, we will continue to monitor pricing trends for products approved under a BLA.

Comment: A commenter requested that CMS codify in regulation that biological products licensed by the FDA under the section 351 BLA process are not considered skin substitutes, are not

considered incident-to supplies under the proposed rule, and will continue to be eligible for separate payment under section 1847A of the Act (generally, ASP+6 percent).

Response: While products licensed under section 351 of the PHS Act may properly be used along with skin substitute application codes, they will continue to be separately paid as biological products using the methodology described in section 1847A of the Act.

CMS also received many comments on the growth in payments for this class of products.

Comment: Many commenters, including ACOs, primary care providers, and health systems, stated that they have witnessed an explosive and unsustainable growth in skin substitute spending, which they attribute to fraud, waste, and abuse. They report seeing products used in clinically questionable circumstances, often by third-party mobile wound clinics that operate without coordination with the patient's primary care team. The commenters identified the ASP-based payment limits as a primary driver of abuse, as it creates financial incentives to use more expensive products, regardless of clinical need. They described a system where manufacturers can launch new, clinically undifferentiated products at inflated prices and offer deep discounts to providers, who then profit from the spread between their acquisition cost and the high Medicare reimbursement rate. The commenters provided examples of significant patient harm resulting from this misuse, including failure to treat the underlying causes of wounds, unnecessary applications, severe infections, sepsis, and even death. They noted a troubling pattern of skin substitutes being applied to vulnerable and terminally ill patients, including those on hospice, where such treatment is inappropriate.

Response: We appreciate the commenters for their input. We believe this policy will dramatically reduce these problematic behaviors in both the physician office and hospital outpatient settings. We also believe this policy has the potential to prevent these harmful practices from occurring in different settings of care, including hospice and home health.

Comment: Several commenters referenced analyses indicating that the vast majority of the spending is driven by a very small number of outlier providers. Commenters referenced one analysis by Tettelbach et al[114] that found that in 2023, fewer than 3 percent of providers accounted for nearly two-

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[114] Tettelbach W, Armstrong DG, Driver V, et al. Safeguarding access, fiscal responsibility and innovation: a comprehensive reimbursement framework for CAMPs to preserve the Medicare Trust Fund. J Wound Care. 2025;34(10):Ahead of Print. doi:10.12968/jowc.2025.0396

thirds of all Medicare spending on these products. The commenters suggested the problem is not broad utilization but isolated misuse by a few bad actors. Based on the concentration of abuse, some commenters stated that CMS should use targeted program integrity measures, such as audits of outlier providers, NPI-level analytics, and stricter enforcement—rather than implementing sweeping payment cuts that penalize all providers and risk harming patient access. Beyond targeted enforcement, commenters recommended systematic oversight mechanisms. A commenter suggested CMS recognize site accreditation through a self-regulatory organization (SRO) to verify adherence to standard of care, documentation protocols, and product handling, analogous to DMEPOS and CLIA accreditation models. The SRO would conduct inspections, publish outcomes dashboards, and impose sanctions. The commenters contend that slashing payment rates is not a fraud control measure and will disproportionately harm compliant providers and the patients who need these products.

Some commenters caution that increased use of skin substitutes is not, in itself, a negative trend. They stated that the growth also reflects expanded access to care for previously underserved populations (like homebound patients) and increased provider awareness of the products' efficacy in healing chronic wounds.

Response: We agree that not all increased use of skin substitutes is improper. However, it is clear that the dramatic growth in spending is not statutorily required and comes without a clear, consistent, and corresponding benefit. The Agency has a responsibility to the public to be good stewards to the Medicare Trust Fund, so CMS has implemented a coordinated effort across several Centers, such as the Center for Medicare, the Center for Clinical Standards and Quality, and the Center for Program Integrity, to address this issue.

Comment: Several commenters offered feedback on skin substitute billing as it relates to value-based care programs such as the Medicare Shared Savings Program. These comments acknowledged support for the proposals relating to the changes in skin substitute payment policy, but expressed concern related to negative impacts to some ACOs who may be disproportionately impacted by skin substitute billing compared to the national trend. Some commenters also made recommendations for revisions to value-based care programs that could address skin substitute billing and similar future scenarios that may

not be captured by the Significant, Anomalous, and Highly Suspect (SAHS) billing activity policy which was finalized in the calendar year (CY) 2025 Medicare Physician Fee Schedule (PFS).

Response: As the commenters referenced, on November 1, 2024, we issued the CY 2025 PFS final rule (89 FR 97710), which included policies discussed under the "Mitigating the Impact of Significant, Anomalous, and Highly Suspect (SAHS) Billing Activity on Shared Savings Program Financial Calculations in Calendar Year 2024 or Subsequent Calendar Years" section of the final rule (89 FR 98191). These policies give CMS the ability to determine that the billing of one or more HCPCS or CPT codes represents significant, anomalous, and highly suspect billing activity for a calendar year that warrants adjustment to calculations made under 42 CFR part 425. Generally, a level of billing for a given HCPCS or CPT code is considered SAHS billing activity when a given HCPCS or CPT code exhibits a level of billing that represents a significant claims increase, either in the volume or dollars, with national or regional impact, and represents a deviation from historical utilization trends that is unexpected and is not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. The billing level must be significant and represent billing activity that would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed (89 FR 98195).

We assessed the impact of an increase in billing to Medicare for skin substitutes and determined that the billing activity for these services does not represent SAHS billing activity for Performance Year (PY) 2024. Skin Substitute billing can have varying impacts on ACOs' performance and could either contribute to increasing or decreasing shared savings and losses, dependent on ACO-level expenditures and national/regional billing activity impacts.

We established the SAHS billing policy to address certain unexplained billing anomalies that could impact program wide calculations, to be invoked in rare and extreme cases when CMS identifies a code that meets the high bar to be defined as SAHS billing activity (89 FR 98196). Payments that are not excluded under the SAHS policy are also reviewable at the ACOs' request if improper payments are identified after the initial determination is made under the reopening policy (42 CFR 425.315).

We will continue to monitor this area with our program integrity partners and to explore options that could mitigate extreme deviations in costs that are outside of the ACOs' control and not addressed through the SAHS policy.

Comment: Some commenters acknowledged that truncation in Medicare Shared Savings Program calculations greatly mitigates a significant amount of outlier billing for skin substitutes. A portion of these commenters also suggested that CMS should apply a lower stop loss truncation threshold in the Medicare Shared Savings Program to address skin substitutes.

Response: To minimize variation in catastrophically large claims, the Medicare Shared Savings Program truncates an assigned beneficiary's total annual Medicare Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare Parts A and B FFS expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year. (42 CFR 425.605(a)(3) and 425.610(a)(4)(ii)).

For all benchmark years and performance years, CMS provides ACOs with the number of assigned beneficiaries with truncated expenditures, the total dollar amounts truncated, and the percentage of total annualized expenditures truncated. We also provide this truncation information for the National Assignable FFS population. We have examined the impact of the truncation policy on skin substitute expenditures and found that over 50 percent of PY 2024 Part B expenditures for skin substitutes were addressed by truncation. Skin substitute expenditures, on average for PY 2024, represent roughly 1 percent of total Parts A and B expenditures for ACOs, and with truncation applied, the average skin substitute expenditures equate to less than 0.5 percent of total Parts A and B expenditures for ACOs. This information indicates that truncation effectively mitigates large spending associated with skin substitute billing.

Comment: Some commenters also provided feedback requesting a formal process and direct channel for ACOs to report fraud.

Response: Medicare Shared Savings Program ACOs are encouraged to report potential fraud or abuse by submitting a complaint to the CMS Center for Program Integrity (CPI), Fraud Investigations Group (FIG), Division of Provider Investigations (DPI) at dpi.intake@cms.hhs.gov. ACOs can also report potential fraud or abuse by submitting a complaint to the Office of Inspector General (OIG) website at

https://oig.hhs.gov/fraud/report-fraud/, OIG hotline at 1-800-HHS-TIPS (1-800-447-8477), TTY at 1-800-377-4950, by fax at 1-800-223-8164, or by mailing to: Office of Inspector General ATTN: OIG HOTLINE OPERATIONS P.O. Box 23489 Washington, DC 20026. ACOs suspecting healthcare fraud, waste, or abuse are encouraged to visit the CMS Center for Program Integrity (CPI) website at https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity for more information.

After careful consideration of public comments, we are finalizing our proposal to limit application of section 1847A of the Act to skin substitutes that are approved as a drug or as a biological product under section 351 of the PHS Act and our proposed edits to the regulations as proposed.

2. Payment Categories Based on FDA Regulatory Category

Paying separately for skin substitutes in the non-facility setting has led to dramatic price increases for these products, as noted previously in this section. Grouping similar products or services into a single billing code and using a single payment amount for them, as we do with many services under the OPPS, some services under the PFS, and all multiple-source drugs under section 1847A of the Act, incentivizes hospitals and prescribers to make the most cost-efficient, clinically effective treatment decision. However, we recognize that grouping dissimilar products and/or services to set payment rates can limit beneficiaries' access to appropriate care, especially when some groups encompass products and services with significant clinical and resource variability. In the case of skin substitutes, no single product among the wide range of products stands out as typical; so we have reviewed several methods to group or classify skin substitutes to determine which best reflects clinical and resource similarities between these products.

We proposed that only skin substitute products licensed under section 351 of the PHS Act will be considered drugs and biologicals for Medicare payment purposes. Furthermore, we proposed that, to reflect relevant product characteristics, we would group skin substitutes that are not drugs or biologicals (that is, anything that is not a section 351 product) using three CMS payment categories based on FDA regulatory categories (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. We have previously noted in rulemaking that CMS has no obligation to categorize products based on the FDA's current regulatory framework (74 FR 60476); but, in this case, we have determined that the FDA regulatory categories provide an appropriate level of distinction for a heterogeneous category of products that exhibit clinical

and resource variability and that categorizing products based on these categories can ultimately improve the accuracy of the relative value units under the PFS. Proposing a payment policy that aligns with FDA's current regulatory framework also provides for predictability and efficiency for purposes of Medicare payment. Payment for new products, as discussed below, could be achieved quickly and consistently by CMS' capacity to immediately recognize the FDA regulatory categories.

a. 361 HCT/Ps

As described previously, 361 HCT/Ps are a subset of HCT/Ps that are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271 and listed in the FDA's eHCTERS. Currently, registered 361 HCT/Ps generally are dressings intended only to cover and protect a wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap. A structural tissue intended for wound care is generally limited to the homologous use of cover and protect in order to be a 361 HCT/P.[115] Intended uses such as wound treatment, promotion or acceleration of wound healing, or serving as a skin substitute would generally be non-homologous uses of structural tissues. Instead, products for such intended uses (for example, the treatment of wounds) generally are subject to PMA or BLA requirements.

b. Devices requiring 510(k) Clearance

A 510(k) is a premarket submission made to the FDA generally by the manufacturer of a device to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval. (FD&C Act sections 510(k), 513(i)). Currently, 510(k)-cleared devices that we are considering for purposes of this proposal generally are dressings intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap. When intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound and otherwise meeting the device definition, generally the FDA's Center for Devices and Radiological Health (CDRH) regulates wound dressings composed of natural biomaterials, including animal and human derived tissue as devices, and they are currently subject to 510(k) requirements. At this time, wound

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[115] See *Regulatory Considerations for HCT/Ps: Minimal Manipulation and Homologous Use, July 2020 (pg. 19)*

dressings have not been 510(k) cleared by FDA for indications such as wound treatment, promotion or acceleration of wound healing, or serving as a skin substitute[116]. Instead, products for such intended uses generally are subject to PMA or BLA requirements.

For the purposes of this policy, we proposed to group any skin substitutes authorized through the De Novo pathway with those cleared under 510(k)s. De Novo classification is a marketing pathway for medical devices for which general controls alone (class I), or general and special controls (class II), provide reasonable assurance of safety and effectiveness. While products authorized through the De Novo pathway have no legally marketed predicate device, devices that are classified into class I or class II through a De Novo authorization may be marketed and used as predicates for future premarket notification (that is, 510(k)) submissions, when applicable. Because of this, we would expect skin substitutes authorized through the De Novo pathway and those cleared under 510(k)s to be similar for purposes of this proposal.

c. Products subject to PMAs

Premarket approval is the most rigorous type of review of a device and generally is required for class III medical devices. Similar to BLA-approved wound care products, PMA-approved wound care products generally are intended to go beyond a simple wound cover to provide some type of direct treatment effect. The FDA has not defined the term "skin substitute." However, the term has been used as a descriptor for certain wound care constructs that are currently approved under a BLA or PMA for treatment of burns or skin ulcers, including ulcers that appear to have failed to heal after standard of care. The intended uses of these products may include scaffold claims, reference to matrix attributes that promote endogenous cell binding, migration, differentiation, or proliferation, and/or activities mediated by matrix-associated regulatory factors that facilitate wound healing. Currently, wound care products intended to interact with the wound to facilitate, promote, or accelerate wound healing generally require approval of a BLA or, in some instances, a PMA. Approval of these products requires demonstration of safety and efficacy for the intended use, which generally requires the performance of clinical studies. So PMA-approved devices can be readily distinguished from 510(k)-cleared devices and 361 HCT/P

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[116] FDA Executive Summary Prepared for the October 26 & 27, 2022 Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Panel Classification of Wound Dressings with Animal-derived Materials (Section 3). Available at download

products, which are intended mainly to cover and protect the wound. They are clinically different, provide different benefits, and would theoretically be used for patients presenting with different clinical scenarios. As discussed, PMA-approved devices also go through a much more rigorous review process before marketing as compared to the substantial equivalence requirements for 510(k)s and lack of premarket review for registered 361 HCT/Ps. This more rigorous review for PMAs, as well as differences in clinical utility, and the associated costs to manufacturers, suggests that the resources involved in furnishing these products could be distinct from 361 HCT/Ps and 510(k)s. We sought comment on our proposal to group skin substitutes (other than those approved via BLA under section 351 of the PHS Act) into three FDA categories, PMA, 510(k), and 361 HCT/P, to set payment rates.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters support grouping skin substitutes based on their FDA regulatory categories, viewing it as a clear, logical, and transparent approach. They believe this method acknowledges the different levels of scientific rigor and evidence required for each pathway and can serve as a surrogate for CMS' own evidence review. This framework would allow CMS to differentiate payment over time based on product characteristics and clinical value, which could incentivize competition and innovation. Some suggest a tiered payment structure where products with more rigorous review (like PMA) receive the highest rates, followed by 510(k) and then 361 HCT/P products. A commenter noted that utilizing FDA's existing regulatory paths and associated compliance activities avoids unnecessary duplication of product assessment resources.

Response: We appreciate the commenters for their support.

Comment: Many commenters opposed using FDA pathways to determine payment, stating that regulatory status does not correlate with clinical effectiveness, outcomes, or resource use. Some commenters noted that none of the skin substitute products approved via the PMA pathway has indications for wound healing in their Instructions for Use or FDA intended use/indications. They point out that some older PMA devices have outdated clinical data and may not be superior to newer 361 HCT/P products or products cleared via the 510(k) pathway. Several commenters stated that 510(k) clearance follows a less intensive pathway than PMA but emphasized that the FDA would never permit

any device for market use unless the 510(k) submission sufficiently demonstrates patient safety and clinical efficacy. Some commenters noted that receiving 510(k) clearance does not imply inferior quality to a PMA product, and that it is inappropriate to consider a PMA product superior simply because it went through more testing. Another commenter explained that a 510(k) device can sometimes be superior to a PMA device for the same indication despite the less rigorous approval process, due to technological advancements, improved materials and design, real-world data, and improved usability and safety features. Several commenters stated that establishing payment based on regulatory pathways creates potential for instability over time because FDA pathway choice is not voluntary—FDA determines which pathway is appropriate for which product. A commenter stated that CMS already determined that FDA approval pathways are not appropriate for Medicare payment policy decisions in its CY 2014 OPPS Final Rule, referencing the discussion at 78 FR 74933 regarding CMS' decision not to use the FDA regulatory pathway to determine OPPS skin substitute payment policy. Overall, some commenters believed this policy could entrench outdated classifications, create perverse incentives to choose products based on reimbursement instead of clinical evidence, and penalize innovative products that use newer, more streamlined regulatory pathways.

Response: We disagree. The FDA's regulatory framework in this context provides an objective and consistent basis on which to group these products for purposes of developing payment rates. Each regulatory path is distinct and provides a specific level/type of information regarding product content and activity that CMS can leverage to inform payment rate decisions. For example, registered 361 HCT/Ps are not approved, cleared or licensed by FDA. There is no premarket review and manufacturing controls are focused on prevention of infectious disease transmission. These products are often dressings generally intended only to cover and protect a wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Similarly, 510(k)-cleared devices[117] relevant to this policy generally are dressings intended only to act as a physical cover to protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. As for 361 HCT/Ps relevant to this policy,

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[117] A 510(k) is a premarket submission made to the FDA generally by the manufacturer of a new device to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device *that is not subject to premarket approval* (sections 510(k) and 513(i) of the FD&C Act).

activity claims are typically limited to that of a physical covering or wrap. They are also not intended to act on the wound to mediate, facilitate, or accelerate wound healing. The 510(k) review assesses equivalence to other 510(k) products and generally does not evaluate activities that otherwise require a PMA or BLA. PMA-approved wound care products generally are intended to go beyond a simple wound cover to provide some type of direct treatment effect. The intended uses of these products may include physical scaffold claims or reference to structural matrix attributes that promote endogenous cell binding, migration, differentiation, or proliferation. Currently, wound care products intended to interact with the wound to facilitate, promote, or accelerate wound healing generally require approval of a BLA or a PMA when it meets the statutory definition of a device. As an example, Integra® Wound Matrix is indicated for the treatment of certain wounds. Approval of these products requires demonstration of safety and efficacy for the intended use, which generally requires the performance of clinical studies. A determination of pathway is informed, in part, by a sponsor's desired indications and ability to prove them.

Notably, unless a product has obtained approval through a BLA, non-homologous use marketing claims are not allowed. Such claims would directly contradict the regulatory status of registered 361 HCT/Ps, because of the criteria in 21 CFR 1271.10(a)(2). Similarly, 510(k)-cleared devices relevant to this policy generally are dressings intended only to act as a physical cover to protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. Descriptions of purported biological healing factors in these products have not been evaluated by FDA; and there is no guarantee that these factors are present or active and, if present, their concentration because these products are not required to have undergone purity or potency assessment performed by FDA. Biological products can differ greatly based on their source material and manufacturing, and it is therefore difficult to generalize any conclusions about their safety and effectiveness beyond those allowed by FDA.

Finally, while we have no obligation to categorize products based on the FDA's current regulatory framework, in this case, we have determined that the FDA regulatory categories provide an appropriate level of distinction for a heterogeneous category of products that exhibit clinical and resource variability for purposes of setting payment rates. This methodology can ultimately improve the accuracy of the relative value units under the PFS while also being predictable and efficient.

Comment: Several commenters emphasized that CMS should acknowledge post-FDA clinical investment if considering FDA pathways as a basis for categorization. A commenter noted investing more than $7.5 million over 6+ years for two seminal RCTs, stating such investment in post-FDA studies alone exceeds application fees of both PMA and BLA products but is not captured in CMS' FDA pathway analysis. Commenters stated that if an overly generalized distinction is drawn between products approved under different pathways, CMS risks disincentivizing manufacturers from further developing clinical evidence and continuing to innovate improved skin substitute products.

Response: We encourage those entities that have made investments in clinical research to work with the FDA to determine if these studies are sufficient to support approval or clearance through the appropriate FDA regulatory pathway and to ensure that essential manufacturing information and controls are available to support approval of a PMA or BLA.

Comment: Several commenters noted that regulatory pathways for skin substitutes have evolved significantly over time, and since CMS does not oversee FDA regulatory pathways, future changes by FDA could inadvertently affect categorization.

Response: We understand that refinements in categorizations for this policy could be warranted in the future and would, at a minimum, address any potential changes through notice and comment rulemaking.

After careful consideration of the comments, we are finalizing our proposal to group skin substitutes (other than those approved via BLA under section 351 of the PHS Act) into three FDA categories, PMA, 510(k), and 361 HCT/Ps, for purposes of developing payment rates in future notice and comment rulemaking, as proposed.

d. Innovative Products

We note that recognizing innovation for supplies through payment policy is complex. It may be difficult to differentiate a truly innovative product from another that offers no true clinical advance. We sought comments on how to properly recognize innovative products through payment policy under the PFS as we continue to assess how best to identify and value innovative products under the PFS. For example, we sought comments on whether skin substitutes with active pass-through payment status under the OPPS and/or those receiving new technology add-on payments (NTAP) under the IPPS should be

paid separately from their FDA category, similar to those approved via BLA under section 351 of the PHS Act, under the PFS. We sought comments on whether these products should meet a substantial clinical improvement standard or whether, consistent with current pass-through policy, a device that has received marketing authorization for an indication covered by FDA's Breakthrough Devices Program would generally represent clinically-relevant innovation sufficient to qualify for a product-specific payment rate. Finally, we sought comments on using either a product's ASP or invoice pricing, similar to how devices with pass-through status are paid in ambulatory surgical centers, or adding a set percentage, similar to the NTAP add-on, to the applicable FDA category's base rate to set payment limits during the period of time that the product is covered by the pass-through and/or NTAP programs.

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Many commenters suggested several mechanisms for CMS to recognize and reward innovation. Several commenters recommended CMS to leverage existing programs like New Technology Add-on Payments (NTAP) and Transitional Pass-Through (TPT) or create a new, parallel program to NTAP/TPT that would provide temporary add-on payments for innovative products used in the physician office setting to ensure site neutrality for new technologies. Also, several commenters suggested payment adjustments could be triggered by specific designations like FDA Breakthrough Device status or by meeting a substantial clinical improvement standard.

Response: We appreciate the comments. We will take them into consideration as we consider how to incentivize innovation in future rulemaking.

3. Alternative Payment Categories

As a conceptually possible alternative to our proposal to group skin substitutes based on FDA regulatory categories for purposes of payment, we considered aligning these products based on their composition, for example, whether they are non-synthetic or synthetic. Two examples provided by interested parties include grouping the products as allografts (for example, amniotic products, cellular products), xenografts (for example, collagen products derived from animals), synthetics (for example, artificial products made from various biomaterials) and grouping the products as human living/cryopreserved tissue, dehydrated human/amniotic tissue, animal xenografts, and

synthetics/polymers. However, as noted previously, skin substitutes are a heterogenous group with an increasing intersection between tissue, bioengineered, and synthetic components. With many products now including both non-synthetic and synthetic components, clear categorization of skin substitutes by composition is no longer feasible. This makes this alternative extremely complex to implement because it would be necessary to determine which category would be most appropriate for each individual product based on the components of its composition and an assessment of the importance of each. In addition, it is unclear if grouping products based solely on their composition would provide accurate differentiation with respect to resource or clinical similarity for the purposes of setting an appropriate payment rate.

Other alternatives we considered include grouping all products together to set a single payment rate or creating two or more categories reflecting product cost, similar to the grouping used currently to set payment rates for skin substitutes in hospital outpatient departments. While these options may offer certain operational advantages for their simplicity, neither recognizes the clinical differences among skin substitutes as reflected by their different intended uses. Paying for similar items and services at a comparable rate is a foundational aspect of our payment systems, but hospital outpatient departments and physicians and other practitioners paid under the PFS could potentially have a financial incentive to use the least expensive skin substitute or the product offering the greatest discount, which could negatively affect patient outcomes and disincentivize innovation in this space if clinical differences are not recognized and differential payments rates are not set. In addition, dividing products by cost relies on pricing set by manufacturers. Especially in light of the dramatic growth of skin substitutes' ASP-based payment limits, this method is unlikely to accurately reflect skin substitute resource costs or clinical similarity.

We sought comments on whether adding certain subcategories to the three proposed FDA categories would improve clinical or resource similarity. One potential example is creating certain subcategories for payment based on one or more FDA device product codes, which is a categorization process that FDA uses to group similar products together. Other examples that have come to our attention include setting unique payment rates for 361 HCT/Ps based on the number of tissue layers (for example, one layer, two layers, and three or more tissue layers) or entirely synthetic products versus non-synthetic products for 510(k)s. If significant clinical or resource differences were identified between products in

one or more of these categories, CMS could create a separate payment grouping for these products for payment purposes.

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Many commenters advocated establishing a single payment rate for all non-BLA skin substitutes. They stated that a single group creates a level playing field, encouraging product selection based on clinical evidence and patient need rather than on which category receives the highest reimbursement. This approach is seen as simpler and avoids the alleged perverse incentives created by past high/low-cost buckets.

Response: While a single rate would result in an administratively simpler policy and likely would result in the most savings, the differentiation of the products in this space supports subgrouping to better ensure access to products in each group. A flat payment rate also reduces the incentive to innovate, perform relevant studies, and seek an FDA approval requiring proof of wound treatment or healing.

Comment: Many commenters oppose a single flat rate, characterizing it as a "one-size-fits-all" approach that fails to recognize the clinical complexity and diversity of products. They believe it would force providers to use less effective products, stifle innovation, and lead to worse patient outcomes, such as higher amputation rates. The commenters state that a single rate below acquisition costs for many products will destabilize office-based care and restrict access.

The commenters suggested various alternative categorization schemes:

- Several commenters suggested a tiered system with 2 to 3 tiers based on product technology, clinical evidence, or cost thresholds. For example, a basic collagen matrix could be in a lower tier, while a cellular product with strong RCT data could be in a higher tier. Another proposal suggested tiers based on whether a product requires one or multiple applications to achieve wound closure.

- Several commenters suggested grouping products based on their composition (for example, human tissue, animal-derived, synthetic) rather than just their FDA pathway. Specific proposals included creating a distinct category for amniotic/placental tissue products or sub-categorizing 361 HCT/P products based on the number of tissue layers (for example, single-layer vs. multi-layer) to better reflect complexity and resource costs.

- A commenter suggested greater aggregation into broader categories like "synthetic" vs. "non-synthetic" would be sufficient.
- A commenter requested a reimbursement framework that provides higher payment for products supported by product-specific randomized clinical trial (RCT) data.
- A commenter suggested implementing a tiered system based on the strength of clinical evidence (for example, number of RCTs) rather than just regulatory pathway.
- Another commenter suggested using the product's FDA cleared/approved label information (for example, product description, including mechanism of action, and indications for use) as well as supporting level 1 human clinical data.

Response: We agree that long-term use of a single, flat rate has the potential to create access issues for specific types of products and reduces the incentive to innovate. However, the options suggested are also problematic. As noted previously, skin substitutes are a heterogenous group with an increasing intersection between tissue, bioengineered, and synthetic components. With many products now including both non-synthetic and synthetic components, clear categorization of skin substitutes by composition is no longer feasible. This makes this alternative extremely complex to implement because it would be necessary to determine which category would be most appropriate for each individual product based on the components of its composition and an assessment of the importance of each. In addition, it is unclear if grouping products based solely on their composition would provide accurate differentiation with respect to resource or clinical similarity for the purposes of setting an appropriate payment rate.

In addition, we have concerns about the quality of many of the product-specific randomized clinical trial (RCT) data that are being produced as well as whether the results can accurately be extrapolated more broadly. As previously discussed, unless a product has obtained approval through a BLA, non-homologous use marketing claims are not allowed. Such claims would directly contradict the regulatory status of registered 361 HCT/Ps, because of the criteria in 21 CFR 1271.10(a). Similarly, 510(k)-cleared devices relevant to this policy generally are dressings intended only to act as a physical cover to protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. Descriptions of purported biological healing factors in these products have not been evaluated by FDA; and there is no guarantee that these factors are present and active or, if present, their concentrations,

because these products have undergone no purity or potency assessment. Biological products can differ greatly based on their source and manufacturing, and it is therefore difficult to generalize any conclusions about their safety and effectiveness beyond those allowed by FDA. While section 1862(a)(1)(A) of the Act directs CMS to make determinations about what is reasonable and necessary for Medicare coverage, FDA's statutorily-defined mandate includes determining the safety, purity, and potency of products such as these. We have neither the resources nor the authority to replicate these functions for payment purposes, and we believe it would be an inefficient administration of government resources to duplicate them.

Comment: A few commenters suggested ways to further subdivide the three FDA categories such as:

- Creating subcategories for 361 HCT/P products based on tissue composition or number of layers to better reflect resource costs.
- Creating a separate category for amniotic/placental tissue products.
- Creating separate categories for products using one or more of FDA device product codes.

Response: We will take these comments into consideration for future rulemaking as we implement this policy and begin to gather new cost data.

We also sought comments on whether products that are not in sheet form are appropriately considered skin substitutes for the purpose of providing separate payment under this policy. Examples include gel, powder, ointment, foam, liquid, or injected products listed in the nontraditional units of cc, mL, mg, and cm^3. We requested feedback on whether these products could be appropriately used as part of the CPT administration codes in the range 15271 through 15278, despite existing CPT coding guidelines limiting their use, and how these units could be paid using the FDA regulatory category groups. For example, assuming these products were appropriate to administer using the noted CPT administration codes or other administration codes, CMS could include products listed in units of cc, mL, or cm^3 in the applicable FDA categories and equate a single cm^2 unit to each cc, mL, or cm^3 for payment purposes. We sought comments on whether other administration codes could be used to appropriately describe services performed using products with units other than cm^2.

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Many commenters recommended CMS include non-sheet product forms (gels, powders, liquids, injectables, 3D-printed constructs etc.) in the definition of skin substitutes eligible for separate payment. The commenters state these products perform similar functions to sheets, offer additional treatment options for irregularly shaped or tunneling wounds, and excluding them from separate payment would stifle innovation and limit physician choice.

The commenters highlighted the following significant challenges with billing for non-sheet products under the proposed framework:

- The proposed per-cm^2 payment does not align with products billed by volume (mL) or weight (mg). Commenters stressed the need for a standardized and fair unit conversion methodology (for example, mL to cm^2 of coverage) to ensure equitable payment and prevent reimbursement misalignment. A commenter suggested that 1 mL of a particular flowable product should be paid at the rate equivalent to 10 cm^2 of a sheet product.
- It is unclear if current surgical application codes (CPT 15271-15278) can be used for non-sheet products, creating a risk they may not be payable at all. The CPT manual explicitly excludes powders and injectables from these codes. The commenters recommended CMS either confirm their eligibility, create alternative CPT/HCPCS G-codes for their application, or develop a crosswalk framework pairing product form with appropriate procedure codes.

Response: We agree that it is important to maintain access to non-sheet products performing similar functions to sheet skin substitutes, in cases where application of these products is part of reasonable and necessary care. These products have the potential to be payable as skin substitutes; but we agree that units, as expressed in a product's coding, are difficult to standardize for payment purposes. Therefore, we will maintain the current coding mechanism for these products and will direct the Medicare Administrative Contractors to determine appropriate payment, which is generally consistent with how these products are currently paid. However, we will continue to evaluate payments for these products to determine if an alternative payment methodology may be better suited to non-sheet products. For now, we are also revising HCPCS code A4100 (Non-sheet form skin substitute, fda cleared as a device, not

otherwise specified (list in addition to primary procedure) to allow billing for non-sheet form skin substitute products that do not yet have a more specific code.

Comment: A commenter recommended that CMS *not* pay separately for non-sheet products as skin substitutes. They stated that procedures for these products are reported with different CPT codes and including them could introduce new opportunities for gaming the system. Another commenter stated that for products cleared via the 510(k) pathway that are classified as gels, liquids, or particulates, reimbursement should follow the existing DME pathway, as these products are not skin substitutes and should not be reimbursed under the skin substitute payment framework.

Response: We disagree that form should be the singular determinant of payment for these products.

Comment: Several commenters stated that CMS has never established a formal definition of "skin substitutes," leading to inconsistent policy, and recommended the agency to develop a comprehensive, clinically grounded definition. Several commenters advocated for defining products based on their clinical function rather than their initial physical form. The commenters cited the cellular, acellular, and matrix-like products (CAMPs) initiative, which defines products by their ability to support tissue regeneration. They stated that a product that forms a "sheet scaffolding for skin growth" in situ (in the wound bed) should be considered functionally equivalent to a product pre-packaged as a sheet. Several commenters recommended that the CPT definition and CAMPS definition be adopted as standard references for skin substitute classification, eliminating outdated distinctions based on initial product form, aligning with scientific consensus, and supporting value-based care focused on clinical outcomes and regenerative functionality. Many commenters stated that the American Medical Association CPT definition of skin substitute grafts explicitly includes "biological products that form a sheet scaffolding for skin growth," specifying the operative standard as whether the product forms a sheet scaffolding, not whether it is originally formulated as a sheet.

Response: We recognize that skin substitutes have been described but not defined in previous rulemaking. While a formal definition would provide certain advantages, it may also prematurely and unnecessarily limit an evolving category of products. For example, definitions that require products to obtain claims of treatment or healing of wounds or scaffold claims would exclude large numbers of even

sheet-form products currently considered by CMS to be skin substitutes for payment purposes. However, we will continue to consider whether a definition or one or more defining characteristics should be identified in future rulemaking.

After careful consideration of the comments, we are finalizing a policy to consider products that are not in sheet form to be skin substitutes for the purpose of providing separate payment as incident-to supplies under this policy. To address the need to establish a payment mechanism for non-sheet form products in the non-facility setting without delay, we will maintain the current coding mechanism for these products and will direct the Medicare Administrative Contractors to determine appropriate payment, which is generally consistent with how these products are currently paid.

4. Establishing RVUs and Initial Payment Rates

Section 1848(c)(2)(N) of the Act provides authority to establish or adjust practice expense RVUs using cost, charge, or other data from suppliers or providers of services, including information collected or obtained under section 1848(c)(2)(M) of the Act. Section 1848(c)(2)(M) of the Act authorizes the Secretary to collect or obtain information on the resources directly or indirectly related to furnishing services for which payment is made under the PFS fee schedule, and such information may be collected or obtained from any eligible professional or any other source. In addition, it allows the Secretary, as he determines appropriate, to use such information in the determination of RVUs. We are relying on these authorities to establish practice expense RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories finalized above based on the volume-weighted average ASP, with no additional markup, as submitted by manufacturers, when available. We have developed initial payment rates for each group based on the weighted, per-unit average of ASPs for the fourth quarter of calendar year 2024. These initial payment rates are listed in the file titled "Skin Substitute Products by FDA Regulatory Category" on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. When ASP was not available, we used the MUC, which we currently use to determine the high-cost/low-cost status for each skin substitute product in the hospital outpatient setting, to calculate the initial rates. While use of hospital cost data departs from the hierarchy of data sources contained in section 1847A of the Act to calculate prices for drugs and biologicals, we note that section

1848(c)(2)(N) of the Act provides authority for us to use this data to establish or adjust practice expense RVUs. In addition, as proposed, skin substitutes in the three FDA regulatory categories would no longer be considered biologicals for the purposes of payment under section 1847A of the Act. We considered using only the MUC data to calculate payment rates for these products. However, when ASP is reported, it may serve as a better estimate of cost across both settings as the ASP reflects sales to physicians as well as hospitals. We sought comments on our proposal to establish PE RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories using ASP, or MUC when ASP is not available, using per-unit averaged pricing data from the fourth quarter of 2024. We also sought comments on whether these calculations, if finalized, should be updated with the most recently available data at the time the final rule is drafted.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported prioritizing ASP data but raised concerns about the reliability of MUC data as a fallback option. These commenters stated that hospital outpatient MUC is less accurate than ASP data submitted in compliance with statute and regulation, citing longstanding challenges with hospital charge compression where reported charges often do not reflect actual acquisition costs. A commenter noted that in some cases CMS did not use ASP data reported to CMS to set Medicare payment limits and recommended the agency to rely on reported ASP data whenever available, given that manufacturers submit this information quarterly in accordance with statutory requirements established by the Consolidated Appropriations Act (CAA), 2021.

Response: When ASP is available and accurately reported, we generally agree that it may serve as a better estimate of acquisition cost across both settings as the ASP reflects sales to physicians as well as hospitals and is net of certain discounts. However, as discussed in section III.A.2 of this final rule, we have had concerns about the accuracy of some reported ASP data; specifically, that manufacturers could be classifying certain costs as bona fide service fees (BFSFs) when they should instead be classified as price concessions, which could artificially inflate ASP. Therefore, we cannot expect that all manufacturers of skin substitute products will continue to report ASP data to CMS each quarter. We disagree with the statement that the outpatient hospital MUC is an inaccurate measure of actual

acquisition costs. CMS uses cost-to-charge ratios specifically to account for variations in hospital markup, and our use of MUC in this case is consistent with how we price other products in hospital outpatient departments. MUC is a useful alternative based on actual claims data when the ASP is not available. Generally, with limited exceptions, when ASP data was available for a product, it was used to calculate a Medicare Part B payment limit and published on the ASP drug pricing files. An exception is for synthetic skin substitutes, which are contractor priced. However, for the purposes of this policy, payment rates were determined using pricing for the 361 HCT/P products only.

Comment: A few commenters expressed concern that using ASP without markup removes appropriate overhead and handling costs. The commenters noted that drugs and biologicals payable under Medicare Part B are statutorily paid at ASP+6%, and using ASP alone eliminates legitimate indirect costs from both OPPS and MPFS systems.

Response: We appreciate these comments and note that overhead costs related to application of these products are included in the facility fees or PE RVUs for the application procedures. A recent Office of the Inspector General report[118] found that, in the third quarter of 2024, a typical beneficiary received 82 units of skin substitutes, meaning that the typical $74 add-on amount per unit alone was worth over $6,000 per patient. Notably, hospitals have been managing these products without separate markup for years through bundled payments.

Comment: A commenter recommended using the arithmetic mean unit cost (AMUC) for products without an ASP, rather than the MUC, which is geometric mean unit cost, to better align with the ASP calculation methodology. Conversely, another commenter recommended using a volume-weighted geometric mean for the overall calculation because it is less influenced by extreme outliers.

Response: We appreciate the commenters for the additional information and may consider these alternatives in future rulemaking.

Comment: A few commenters supported using Q4 2024 ASP data as the foundation for CY 2026 rate calculations.

Response: We appreciate the commenters for their support.

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[118] Office of Inspector General, U.S. Department of Health and Human Services. *Medicare Part B Payment Trends for Skin Substitutes Raise Major Concerns About Fraud, Waste, and Abuse.* September 10, 2025.

Comment: Several commenters criticized the use of Q4 2024 ASP data. Some suggested using data from before the recent price explosion (for example, CY 2019, 2022, 2023, or Q4 2023) to establish a more reasonable baseline free from market distortions. Other commenters stated that more current data (for example, Q3 2025) should be used to reflect real-time market conditions reasoning that using older data could introduce a systemic underpayment.

Response: We agree that much earlier datasets (for example, CY 2019 PFS) do not reflect a significant portion of the recent growth in products and payments for this class of products. However, these datasets also do not reflect many new products that may represent quality additions to the market. To avoid this issue, we instead calculated initial rates using hospital outpatient utilization to weight how much each product's price contributes to the proposed payment rates for skin substitutes. In this setting, skin substitutes are currently paid in two groups (high- and low-cost) to incentivize cost-effective product selection. No similar incentive currently exists in the non-facility setting for physicians and other suppliers billing under the PFS. That is why we consider hospital outpatient utilization a better source to weight the average among the products. We used the fourth quarter of 2024 because it was the most recent, substantially complete quarter of data and the most complete ASP reporting is typically in the fourth quarter of each year. Finally, use of a later quarter's file would not have allowed us to match up time periods for utilization patterns, and interested parties were given an opportunity to review and comment on that proposed rate.

After careful consideration of the comments, we are finalizing our proposal to establish PE RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories using ASP, or MUC when ASP is not available, using per-unit averaged pricing data from the fourth quarter of 2024 as proposed.

As we proposed to implement this policy for CY 2026 in a site-neutral manner across both the non-facility setting under the PFS and hospital outpatient setting under the OPPS, we are including all products used in either setting to calculate the rates. However, when product-specific utilization across both settings is used to calculate volume-weighted average payments, the result is an apparent rank order anomaly; despite having a more rigorous regulatory review process and receiving indications to treat and heal wounds, the PMA category has the lowest average payment. We are concerned that use of the novel

pricing practices noted previously in this section has resulted in a decoupling of actual resource costs from the ASP. To address this, as a short-term measure, we proposed to weight the product-specific utilization in calculating the rates using the proportions from only the hospital OPPS data and establish for CY 2026 a single payment rate that would apply to all skin substitute products in the three FDA regulatory categories. We believe the OPPS utilization data may better predict utilization patterns under our policies for non-facility settings because, similar to our final policy, these products are already grouped together for payment purposes under the OPPS. By grouping skin substitutes into high- and low-cost groups in the OPPS, hospitals are incentivized to choose either the lowest-cost, clinically appropriate product in the low-cost group or the lowest-cost, clinically appropriate product in the high-cost group. No similar incentive currently exists in the non-facility setting for physicians and other suppliers billing under the PFS. As the policies are intended to mitigate the current patterns of use in the non-facility setting by establishing payment rates for the products in groups instead of individually, we do not believe it would reflect the expected resource costs involved in providing care if we were to base the initial rates on utilization data from the non-facility setting that may have been skewed by aggressive and/or improper billing practices that would be less likely to exist under our policies. For these reasons, we proposed to initially use hospital outpatient utilization to weight how much each product's price contributes to the proposed payment rates for skin substitutes cleared through the 510(k) pathway, registered 361 HCT/Ps, or approved under a PMA. We sought comments on the use of the hospital outpatient product utilization patterns to set payment rates for these products under the PFS.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters, including MedPAC, strongly support using only OPPS utilization data to set the initial rate. They agree with CMS that utilization data from the physician office setting (PFS) has been distorted by the profiteering practices of certain skin substitute product manufacturers. They believe OPPS data is a better predictor of use patterns under a grouped payment approach because hospitals are already incentivized to choose lower-cost products within the existing high/low-cost categories.

Response: We appreciate the commenters for their support.

Comment: A majority of commenters strongly opposed the exclusion of physician office data, stating that this methodology is flawed, biased, and not representative of real-world practice. The commenters make several key points:

- The vast majority of skin substitute utilization (nearly 90 percent in Q4 2024) occurs in the physician office setting, so excluding data from the predominant site of service is unreasonable.
- OPPS data is itself skewed. The current bundled payment system in hospitals disincentivizes the treatment of larger wounds in the hospital setting and the use of more advanced, higher-cost products, artificially driving down the average cost in that setting.
- Hospitals can negotiate lower prices through GPOs, which are unavailable to smaller physician offices. Basing a national rate on hospital acquisition costs will create a payment rate that is unsustainable for non-facility providers.
- Using data from only one setting to create a site-neutral rate for all settings is methodologically unsound and works against the stated goal of a consistent payment approach.

The prevailing recommendation from those opposed to the OPPS-only method is to use a blended approach that incorporates utilization data from *both* the physician office and hospital outpatient settings. To address CMS' concerns about distorted office data, they suggest using safeguards like trimming outliers or using data from a time period before the recent spending explosion (for example, 2019 or 2022).

Response: Although skin substitute products are more commonly used in the physician office setting, as we stated in the CY 2026 PFS proposed rule (90 FR 32593), we believe that separate payment for these products in the non-facility setting has led to problematic practices that are mitigated by the current OPPS policy of paying for skin substitute products in either high-cost or low-cost groupings. We believe OPPS utilization data better reflects the utilization associated with grouping these products into categories for purposes of payment. As we stated in the CY 2026 PFS proposed rule, we do not believe it would reflect the expected resource costs involved in providing care if we were to base the initial rates on utilization data from the non-facility setting. Once updated use patterns reflecting this policy are available to calculate rates, we proposed to use all relevant products and the combined product utilization patterns

(OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three categories.

Comment: A few commenters recommended using guardrails to ensure the methodology does not inadvertently embed misaligned historical incentives. These commenters believe CMS has several options to mitigate fraudulent and abusive practices, including trimming for outliers that may signal falsely high utilization, using data only from claims that meet established criteria for completeness and accurate coding, and capping counted square centimeters at 120 to150 percent of the CPT-implied wound size.

Response: Because we are using OPPS utilization patterns and the OPPS does not currently stratify payment for each individual product, and, by doing so, promote more efficient care, we believe many of these problematic claims will be mitigated. However, as this policy unbundles skin substitutes from their application codes and pays for them separately, we are concerned about the potential for overuse and waste. We invite additional thoughts about how best to mitigate these issues while products are separately paid and note that we will be monitoring usage as compared to CPT coding moving forward.

Comment: A commenter questioned why all outpatient facility volumes were not used for this policy, including critical access hospitals and other providers, noting that coding for products would be on those claims as well.

Response: We appreciate the comment. We developed the proposed rate using hospital outpatient data based on PPS data since, as we stated previously in this section, we believe the structure of payment under the OPPS with payment for these products grouped into two categories best reflects use not potentially influenced by the previous system. Using OPPS data only allows for a consistent data set that reflects the majority of Medicare hospital outpatient services, across a wide variety of geographies and areas of the country.

After careful consideration of the comments, we are finalizing our proposal on the use of the hospital outpatient product utilization patterns to set payment rates for these products under the PFS as proposed.

We also proposed for CY 2026 to establish the same initial rate for each group of skin substitutes, including 510(k)-cleared devices, registered 361 HCT/Ps, and PMA-approved devices. To ensure we are

not underestimating the resources involved in using these products in furnishing care, we are proposing to use the highest of the calculated volume-weighted average payment amounts for 510(k)-cleared devices, 361 HCT/Ps, and PMA-approved devices to set initial payment valuations. As the 361 HCT/Ps have the highest volume-weighted average payment amount, this average payment rate is reflected in the proposed initial payment rate below. However, we note that, in future notice and comment rulemaking, we intend to propose using claims data to set payment rates for products in these three categories, which would likely result in payment valuations that diverge based on the updated data. Another alternative is to set the payment rate for products in these categories at the volume-weighted average for all three categories, resulting in a lower initial payment rate for all three groups of products. We sought comment on our proposal to use the 361 HCT/P volume-weighted average payment amount to set the initial payment rates for products in all three categories as well as the alternative of using a pooled average of the three categories to set the initial payment rates.

Alternatively, while the ASP pricing files show that skin substitutes across all three of the FDA regulatory categories have increased in cost substantially since 2019, unlike the self-determined 361 HCT/Ps and 510(k)-cleared devices, there has not been a substantial increase in the number of skin substitutes with approved PMAs. Consequently, it is possible that the non-facility utilization of the skin substitutes with approved PMAs is not as distorted as the utilization of the other kinds of skin substitutes. Setting a separate payment rate for this category using combined product utilization patterns (from both OPPS and non-facility settings), would result in a higher initial payment rate for the PMA category. This would rationally order the FDA regulatory categories, based on clinical considerations and some indicators of resource cost, until pricing data can be stabilized. We sought comments on this alternative policy option

Under the PFS, payment rates are determined based on work RVUs, PE RVUs, and MP RVUs multiplied by their respective GPCI adjusters and then converted into dollars through multiplication by the conversion factor. For skin substitutes that would be valued and paid as incident-to supplies under our proposal, the practitioner work associated with the application of the skin substitute is already accounted for in the valuation of the application codes themselves (CPT codes 15271-15278), so we did not propose work RVUs for the codes that describe the products involved in furnishing the application service. Rather

than using the established PE methodology to derive PE RVUs from work, direct PE inputs, and the PE/HR data (as described in section II.E. of this final rule), we instead proposed to use our authority under sections 1848(c)(2)(M) and (N) of the Act to establish PE RVUs for these supplies using rates calculated from a combination of OPPS cost data and ASP data weighted by OPPS volume. For the specific PE RVUs, please see Addendum B of this final rule available on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For malpractice RVUs, we generally believe that the malpractice resources are already reflected in the MP RVUs associated with the application codes, but because the standard PFS methodologies assign a minimum of .01 MP RVUs to all codes except add-on codes (75 FR 73276), we proposed an MP RVU of 0.01 for these supplies consistent with the rounding convention. We also sought comments on whether we should consider treating the codes describing skin substitute products as add-on codes to the current CPT application codes. This would more clearly indicate that the only skin substitute products to be paid for and treated as supplies by Medicare are those used in conjunction with the already existing CPT administration codes. If we were to treat these codes as add-on codes to the application codes, we would effectuate this by assigning a global indicator of ZZZ to the skin substitute codes under the PFS. If we were to finalize these codes as add-on codes, we would assign 0 MP RVUs to them, consistent with existing policy regarding add-on codes.

The final PE and MP RVUs would result in an initial payment rate of approximately \$125.38/cm^2 for skin substitute products in all three FDA regulatory categories (including PMA-approved devices, 361 HCT/Ps, and 510(k)-cleared devices) prior to the application of the geographic adjustments. Again, the proposed PE and MP RVUs are available in Addendum B of this final rule. We sought comments on these proposed initial values.

We determined these values using product pricing and volume for skin substitutes from paid claims with dates of service in the fourth quarter of 2024 because it was the most recent, substantially complete quarter of data. For professional claims, we excluded claims without a positive line-level allowed amount, so that we did not inadvertently include volume without presumed costs in the calculation. In addition, in reviewing the ASP pricing files from the first quarter of 2017 through the first quarter of 2025, the most complete ASP reporting is in the fourth quarter of each year. To determine the

payment rates, we first used a product's ASP if it was available. If the ASP rate was missing, we used the 2024 MUC for the HCPCS code. We then calculated a single rate for each FDA category by taking the volume-weighted average of the rates for the applicable codes using the hospital outpatient utilization to weight each category. We note that if rather than using the final quarter of CY 2024, we alternatively, were to use pricing and volume from all four quarters of 2024 to determine proposed rates, the rate for all categories would be approximately \$114.87/cm^2. Using a pooled payment rate across all three categories would result in a rate of approximately \$65.85/cm^2, while splitting the categories to pay the PMA category using the combined product utilization patterns and the 510(k) and 361 HCT/P categories using the OPPS utilization patterns would result in rates of approximately \$259.47/cm^2 and \$125.38/cm^2 respectively. We sought comments on our proposed process to calculate initial payment rates as well as these alternatives.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that the proposed payment rate of approximately \$125 per square centimeter is far too low and unsustainable. The commenters state this rate is well below the actual acquisition and operational costs for most providers, especially smaller practices and mobile units without hospital purchasing power. If implemented, they warn it will make offering these therapies financially impossible, forcing practices to close and severely restrict patient access to care, particularly for homebound, rural, and underserved populations. This could lead to worse outcomes, including more amputations, infections, and hospitalizations, ultimately increasing overall Medicare costs.

Instead, many commenters proposed higher rates. A frequently cited alternative, based on independent analyses, was a payment range of approximately \$478 to \$704/cm^2. The commenters stated that this range would still generate over \$100 billion in Medicare savings over a decade while preserving patient access and innovation. Other suggestions fell within a similar range, such as \$500/cm^2, \$500 to \$640/cm^2, or up to \$973/cm^2. Another commenter suggested that CMS calculate the payment rate for skin substitute products using a trimmed mean approach, excluding the top and bottom 10 percent of reported prices of 130 skin substitute products, to eliminate outliers and better reflect fair value. They suggested that the resulting average price of \$865/cm^2 would reflect a fair market average and suggested CMS set a

higher allowed amount of approximately $1,080/cm^2 to ensure providers can sustain services under Medicare's 80 percent payment structure. A few commenters also suggested that the 20 percent copayments should be waived for treatment with skin substitute products. Several commenters supported reimbursement methodology outlined in Senate Bill 2561 (Skin Substitute Access and Payment Reform Act of 2025), which would establish rates based on Q4 2023 ASP data volume-weighted according to actual utilization in both the professional and hospital outpatient settings. The commenters stated that the methodology prescribed in the legislation would result in a payment range of approximately $500 to 700/cm^2. Some commenters proposed tiered pricing structures for HCT/P 361 products based on configuration, with recommendations ranging from $400 to $500/cm^2 for single-layer amniotic products to $800 to $900/cm^2 for full-thickness grafts. Other commenters recommended tiered frameworks incentivizing manufacturers to pursue rigorous FDA pathways with reimbursement increases of 25 to 100 percent over base pricing of $400 to $900/cm^2. Several commenters cited crosswalks to similar products as valid data points. Commenters noted that CPT codes for placing amniotic membrane on ocular surfaces (65778 and 65779) use amniotic membrane allograft supplies paid at $835 and $1,149 in CY 2025. Since typical amniotic tissue grafts placed in eyes are 14mm diameter discs with surface area of approximately 1.5 cm^2, commenters calculated these rates equal $557 to $776 per square centimeter, stating it would be arbitrary and capricious for CMS to price amniotic tissue grafts for eyes at significantly higher rates than same tissues used for chronic wounds. Some suggest using the higher rate CMS calculated for one of the other FDA categories ($259.47/cm^2) as a more reasonable starting point.

Response: We appreciate the many detailed comments we received on this issue, but we do not agree that higher payment rates are warranted at this time for several reasons. First, most of these payment rates use non-facility utilization patterns that have been significantly distorted in recent years by problematic practices. Incorporating this data into the payment rate would embed these practices into the policy. These practices have largely been mitigated in the OPPS utilization patterns, which is why they were used to develop an initial rate for this policy. Second, manufacturers have demonstrated the ability to offer products well below current ASP levels, which indicates that current prices have considerable room for compression without risking product availability or access. Third, there are a significant number of products with current ASPs below this policy's payment rate already. Finally, many of the more

expensive products on the market fall into our 361 HCT/P and 510(k) product categories, but their function is typically limited to that of a physical covering or wrap. These products are not intended to act on the wound to mediate, facilitate, or accelerate wound healing and the justification for these rates is unclear. However, we do not agree that a product used to cover the cornea and prevent scarring and others used to prevent infection should necessarily be priced at the same rate. Once updated use patterns reflecting this policy are available to calculate rates, we will use all relevant products and the combined product utilization patterns (OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three categories, and we will continue to monitor this product class and propose additional adjustments to the policy as necessary in future rulemaking.

Comment: Many commenters expressed concern that a low, uniform payment rate would stifle innovation. They stated that it would discourage investment in research and development for next-generation products, as manufacturers would be unable to recoup the significant costs associated with bringing novel therapies to the market. They stated that this could penalize innovative therapies, favor older and lower-cost alternatives, and ultimately limit patient access to more effective technologies. In contrast, some commenters believe the proposed changes will rightly shift the focus to value-based innovation. They stated that true innovation lies in making highly efficacious products at a reasonable price, not just launching increasingly expensive ones. They contend that manufacturers should be required to show robust clinical evidence to justify payment, and the current proposal encourages this shift.

Response: We agree that our policy should incentivize innovation in this class of products. As previously noted, in future notice and comment rulemaking, we intend to use claims data to set separate payment rates for products in the three categories, which would likely result in payment valuations that diverge based on the updated data. As the PMA category is by far the smallest, we would anticipate less competition and potentially higher payment rates for those products. In addition, products marketed under the BLA pathway would continue to receive separate payment under the ASP methodology described in section 1847A of the Act. We also welcome continued dialogue on ways to differentiate a truly innovative product from another that offers no true clinical advance as well as on how to properly recognize innovative products through payment policy under the PFS as we continue to assess how best to identify and value innovative products under the PFS.

Comment: A smaller group of commenters supported the proposed rate, and some even advocated for a lower one. Some commenters cited published cost-effectiveness analyses. A commenter noted a study concluding that interventions using skin substitutes with payment limits below $140 per square centimeter were dominant (less costly, better outcomes) compared to typical care; and, based on cost-effectiveness threshold of $100,000 per quality-adjusted life year, interventions were cost-effective with payment limits up to $430 per square centimeter. A commenter stated that a rate of $125/cm² seems "more than reasonable" given that manufacturing costs for some products are much lower. Several ACOs and provider groups recommended that CMS use a "pooled" average across all product categories, which would result in an even lower rate of ~$65/cm², to more accurately reflect resource costs and further curb overspending. Another commenter recommended a rate of $75/cm².

Response: We appreciate the commenters for their feedback. We disagree that further reduction of the initial payment rate is prudent before updated claims data reflecting the results of this policy can be gathered and evaluated.

Comment: There was a split on whether to use a single rate for all products. Many commenters supported finalizing a single, standardized payment rate for all non-BLA products. They stated this creates a level playing field, where clinical choice is driven by evidence and patient need, not by which category has the highest reimbursement. This approach is seen as simpler and less likely to repeat the high-cost/low-cost bucket system of the past. Some commenters requested that after setting an initial rate for 2026, CMS should maintain that single rate for two additional rulemaking cycles before recommending any changes, allowing time to carefully evaluate claims data. Some comments requested moving to tiered payment rates in CY 2027 after setting an initial flat payment rate for CY 2026. Other commenters suggested for immediate implementation of a tiered or differentiated payment system in 2026, rather than waiting until 2027. They believe this better reflects product complexity and clinical evidence and avoids treating all products as if they are the same.

Response: While a single rate would result in an administratively simpler policy and likely would result in the most savings, the differentiation of the products in this space suggest for subgrouping to better ensure access to products in each group. A flat payment rate may also reduce the incentive to innovate, perform relevant studies, and seek an FDA approval requiring proof of wound treatment or

healing. While we do intend to use claims data to set separate payment rates for products in the three categories in future notice and comment rulemaking, we are concerned that use of the novel pricing practices noted previously in this section has resulted in a decoupling of actual resource costs from the ASP. To address this, as a short-term measure, we proposed to weight the product-specific utilization in calculating the rates using the proportions from only the hospital OPPS data and establish for CY 2026 a single payment rate that would apply to all skin substitute products in the three FDA regulatory categories. We will propose rates for these three categories through notice and comment rulemaking once updated use patterns reflect this policy.

Comment: To avoid sudden market disruption and access issues, some commenters recommended phasing in the payment reduction over several years (for example, 3 years). This would blend the old ASP+6% payment with the new flat rate over time, giving providers and manufacturers a chance to adapt.

Response: We do not agree that a phased-in approach is necessary. The nearly 40-fold increase in spending on these products has been concentrated in just the past several years. To allow these damaging practices to continue, even in part, for years longer may only serve to unnecessarily delay efficient purchasing, appropriate utilization, and product selection based on clinical need.

Comment: Several commenters opposed applying geographic adjustments to skin substitute product payments, stating that product costs do not vary by location as manufacturer pricing remains consistent regardless of clinical site or geography. Several commenters stated that geographic adjustments would create access disparities, particularly harming rural and underserved communities where patients may have greater needs but providers face lower reimbursement rates. Commenters recommended that CMS exclude skin substitutes from geographic RVU adjustments, noting that while professional service costs may vary by location, product costs do not.

Response: Section 1848(e) of the Act requires that the PFS include geographic adjustment factors and account for geographic variations in the costs of furnishing services. As discussed in section II.N of this final rule, the PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs among the PFS localities as compared to the national average of these costs. We recognize that the variations in relative resource costs based on geography are not necessarily proportionately the same across all kinds of PFS services. We appreciate the information provided by the

commenters as these dynamics apply specifically for these products and may consider adjustments for future rulemaking.

Comment: Some commenters suggested that CMS' alternative approach of establishing payment for skin substitute products as an add-on code to current CPT application codes could have the added benefit of eliminating the bifurcated HCPCS coding system for skin substitute products (that is, Q-codes vs. A-codes, two different types of Healthcare Common Procedure Coding System (HCPCS) codes used for billing and administrative purposes), which has created significant administrative burdens and confusion for physicians and MACs, and streamlining administrative requirements when physicians utilize and submit claims for skin substitute products. MedPAC supported paying for skin substitute products as an add-on service rather than as a standalone service, noting that paying for these products as a standalone service would require CMS to assign 0.01 MP RVUs to the payment for each unit of the skin substitute the clinician applies. MedPAC stated that while 0.01 is a small amount per unit, these products are often billed in multiple units, which could result in too many malpractice RVUs being allocated to these products. As an add-on code, the service would have its own PE RVUs but would be assigned 0 MP RVUs. Some commenters stated that CMS inappropriately assigned a MP RVU of 0.01 to each of the 235 supply codes and strongly rejected this proposal, recommending that CMS convert the global period for the supply codes to reflect a ZZZ add-on code and eliminate the MP RVUs entirely, stating it is unfair to dilute the distribution of MP RVUs away from physicians to supply codes.

Response: We appreciate all of the information provided by commenters as to whether skin substitute codes should be considered add-on codes and therefore would not have any MP RVUs assigned. We agree that the resource costs associated with malpractice insurance would be reflected in the MP RVUs associated with the application code, and so we are finalizing conversion of all skin substitute products codes to add-on codes. The RVUs and indicator statuses can be found in Addendum B in the Download files for this final rule under CY 2026 PFS Final Rule Addenda at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.

Comment: Several commenters raised concerns about maintaining payment consistency between PFS and OPPS. Commenters noted that OPPS receives annual market basket adjustments while PFS does

not, questioning how CMS would prevent the rates from diverging over time and creating site-of-service incentives.

Response: We appreciate the commenters bringing these concerns to our attention, and while we remind readers that variations in the annual update mechanisms for Medicare payment systems are generally determined by statute, we may consider the interaction between the update factors and the development of future proposed rates for these products for future rulemaking.

Comment: Several commenters highlighted minor discrepancies in the RVUs displayed in the proposed rule addendum and the dollar amounts described in the proposed methodology. For example, the proposed rule addendum shows 3.71 RVUs (or $124.61) per square centimeter for QPs and $123.99 for non-QPs, both below the proposed $125.38 as described in the rule. The commenters questioned which conversion factor CMS intended to use, noting that many practitioners do not qualify as QPs.

Response: We appreciate the commenters for this feedback. We agree that many practitioners would not qualify as QPs, therefore we would generally view the non-QP conversion factor as the default conversion factor. Additionally, we acknowledge the minor arithmetic discrepancies between the dollar amounts described in this final rule and the RVUs in the addendum. These slight discrepancies, smaller than 1 percent of the overall rate, were the result of uneven incorporation of refined data in the development of the addendum files. The proposed rates included several data points and reflected an approximate rate. We appreciate the commenters pointing these out, and we will ensure the addendum are appropriately updated.

Comment: Several commenters raised concerns about transparency in CMS' rate calculation. The commenters stated that the information provided was insufficient to understand or recreate CMS' calculations. Some commenters were unable to replicate the $125.38 rate, while others replicated it within 1 percent. A commenter noted that a supplemental document posted August 11, 2025, created additional confusion by describing steps the proposed rule indicated were not performed and contradicting information in the rule itself. The commenters stated CMS did not publish comparison files showing ASP versus MUC values for each product, which are important for evaluating the proposal. Many commenters recommended CMS provide complete methodology details to enable meaningful comment, with some stating that the lack of transparency violates APA requirements for well-reasoned analysis.

Response: We disagree with the commenters' statement that CMS was unclear in the description of the methodology used to calculate the proposed initial payment rate of $125.38/cm^2. We provided a substantial amount of detail on our calculations in the proposed rule, including the HCPCS codes that were pulled and the data sources to provide even more detail. We released a supplemental document, "Additional Description of Calculation of Proposed Payment Rates for Skin Substitutes" on the CMS website at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-p, which further explains the methodology used to calculate the payment rates for skin substitute products. Several commenters were able to replicate our methodology and stated that they were able to approximate the proposed payment rate based on the information provided.

Comment: Commenters identified several products that CMS had incorrectly categorized in its published lists, suggesting the agency correct these errors before finalizing any rate-setting based on the categories. Commenters noted that HCPCS codes Q4107, Q4108, Q4116, Q4122, Q4142, Q4146, Q4147, Q4159, Q4198, Q4201, Q4225, Q4226, Q4232, Q4238, Q4276, Q4282, and Q4297 were misclassified into the wrong FDA categories. The commenters stated these errors lead to inaccurate payment rates for all products in affected categories and suggested CMS correct all assignments before finalizing the rule.

Response: We appreciate the comments. We reviewed the information provided and acknowledge there were some discrepancies in the grouping of some HCPCS codes for particular products in the proposed rule. We conducted additional analyses shifting those FDA categorizations, including those suggested by commenters, some of which caused volatility resulting in significant reductions compared to the proposed rule rates.

After careful consideration of the comments, for CY 2026 we are finalizing rates consistent with the groupings illustrated in the proposed rule in the interest of transparency and consistency. Prospectively, however, we will designate these HCPCS to the groupings suggested by commenters. We are finalizing our proposal to use the 361 HCT/P volume-weighted average payment amount, based on the grouping of HCPCS codes in the proposed rule, to set the initial payment rates for products in all three categories and calculate the initial payment rates as proposed. We also note, that consistent with the proposed rule, we maintained use of hospital

claims volume from services incurred during the fourth quarter 2024. We used an updated version of the hospital claims volume as this is the most recent data available as of the time of drafting this final rule. We also used fourth quarter 2024 ASP data and 2026 MUC data (based on 2024 claims data), when ASP data was not available, as proposed. Given the volatility around skin substitute products due in part to gaming and the proliferation of coding already discussed in this final rule, even small changes to the methodologies, such as using a different quarter of ASP data or updating the regulatory categories of only 17 of over 200 skin substitute products, can result in significant changes to the payment rate. Accordingly, we believe maintaining the same framework for setting the payment rate that was used for the proposed rule, including the FDA regulatory categorizations and the same time periods for pricing, is consistent with the proposed rate on which the public had an opportunity to comment on compared to the volatility that could occur using different definitions. Prospectively, one of our policy goals is to promote greater stability in the payment for skin substitute products. Therefore, consistent with the framework for the methodology proposed in the CY 2026 PFS proposed rule, we are finalizing a final payment rate for CY 2026 of $127.28/cm^2.

The full list of codes with the payment groupings used in developing the proposed and final rate calculations are available on the CMS website. Likewise, the full list of codes and their payment groupings prospectively are available on the CMS website and in Addendum B.

After careful consideration of the comments, we are finalizing our proposal to use the 361 HCT/P volume-weighted average payment amount to set the initial payment rates for products in all three categories and calculate the initial payment rates as proposed with the exception of updates to several code classifications and updated with the most recent data available as of the time of drafting this final rule, which resulted in a final payment rate for CY 2026 of $127.19/cm^2. Specifically, we used 2026 MUC data (based on 2024 claims data) for the fourth quarter 2024 ASP data, weight by hospital outpatient claims volume.

We proposed to maintain the current structure of HCPCS codes for skin substitutes, including a process to introduce new product-specific codes and propose initial valuation based on the typical

resource costs (that is, those reflected in ASP and MUC data) of the groups associated with each skin substitute's HCPCS code. For a complete list of codes and FDA categories, please see file titled "Skin Substitute Products by FDA Regulatory Category" available on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Individual HCPCS coding remains necessary to provide identification on claims and track each product's cost. This will also allow effectuation of any applicable coverage policies and improve our ability to determine if any refinements in payment categories would be appropriate in future rulemaking. For the most part, the resources for incident-to supplies are included in the total RVUs of a procedural code or are packaged under the OPPS. However, this proposed approach is not entirely novel, since Medicare pays for various components of services through the use of separate HCPCS codes and/or payment modifiers. The most obvious examples of these kinds of payment and coding splits occur in diagnostic tests and radiation treatment services, but there are also many examples in the PFS of add-on codes with RVUs primarily driven by the costs of particular items, including disposable supplies. In this case, the full range of resource costs for the services would not be included in the RVUs or payment amount for a single code but rather spread across several codes, namely a base code and one or more add-on codes. In this case, the application base codes would be reported with an add-on or multiple add-on HCPCS codes associated with skin substitutes. For example, CPT code 15271 (application of skin substitute graft, leg or ankle) would be reported with a PE-only add-on code that includes the resources involved in using the skin substitute product. (Such PE-only codes are designated with a PC/TC indicator of 3 and are only paid under the PFS in the non-facility setting. The same HCPCS code would be separately reportable in the hospital outpatient setting but not paid under the PFS.)

We proposed that new HCPCS codes describing skin substitutes would be categorized based on whether they are PMA-approved, 510(k)-cleared, or registered 361 HCT/Ps and the RVUs that apply to that category would be applied to the new code at the next quarterly update. Any change to the RVUs associated with each group would be subject to annual notice and comment rulemaking. Currently, HCPCS Level II coding applications are submitted and reviewed during the quarterly and biannual coding cycles. We post our coding determinations for drugs and biologicals on a quarterly basis, and do not

routinely review those applications at a HCPCS public meeting. For non-drugs and non-biologicals, we post our coding decisions on a biannual basis. For our biannual cycles for non-drugs and non-biologicals, we post preliminary coding determinations then invite feedback on those preliminary coding determinations at a biannual HCPCS public meeting; final coding determinations are posted following the HCPCS public meeting. CMS has been reviewing skin substitutes marketed as 361 HCT/Ps in the quarterly drugs and biologicals coding cycle and 510(k)-cleared skin substitutes in the biannual, non-drugs and non-biologicals coding cycle. Beginning January 1, 2026, we proposed to review HCPCS Level II coding applications for all skin substitutes marketed as 361 HCT/Ps through our biannual coding cycle for non-drugs and non-biological products, rather than on a quarterly basis. Skin substitutes that received a 510(k) clearance, PMA approval, or a granted De Novo request would continue to be evaluated in the biannual HCPCS Level II coding cycles. Therefore, under this proposal, CMS would evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles. Should any products come to market under the BLA, NDA, or ANDA pathways that could potentially be considered skin substitutes, CMS would instead review them in a quarterly HCPCS Level II drugs and biologicals coding cycle. Before a code is assigned, not otherwise classified (NOC) HCPCS codes Q4431 (Unlisted PMA skin substitute product), Q4432 (Unlisted 510(k) skin substitute product), and Q4433 (Unlisted 361 HCT/P skin substitute product) would be used and the CMS MACs would assign the appropriate payment based on the product's FDA regulatory category.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to maintain the current structure of HCPCS codes for skin substitutes. Several commenters recommended that CMS eliminate the bifurcated coding system where some products have "Q" codes and others have "A" codes. They recommended CMS to reassign all skin substitute products to "Q" codes to reduce administrative burden and confusion for providers and MACs.

Response: We appreciate the feedback. We will take comments about the coding differences between the products into consideration for future rulemaking.

Comment: Several commenters opposed CMS' proposal to shift the HCPCS Level II coding application review for 361 HCT/P products from a quarterly to a biannual cycle. Commenters stated that maintaining the quarterly cycle is essential for timely patient access to new therapies, supporting innovation, and aligning with the faster review cadence used for drugs and biologics. Commenters stated a biannual cycle would create lengthy delays (18 months or more) for new products to get a code and be reimbursed, creating a barrier to market entry. Commenters stated that all skin substitutes, regardless of regulatory status, should have the same quarterly review process to maintain a level playing field.

Response: We disagree. We post our coding decisions for all non-drugs and non-biologicals on a biannual basis. While we have been reviewing skin substitutes marketed as 361 HCT/Ps in the quarterly drugs and biologicals coding cycle, under this policy, unless a skin substitute is approved as a drug or as a biological product under section 351 of the PHS Act, we would consider it an incident-to supply for payment and coding purposes under the PFS. Beginning January 1, 2026, we will review HCPCS Level II coding applications for all skin substitutes marketed as 361 HCT/Ps through our biannual coding cycle for non-drugs and non-biological products, rather than on a quarterly basis. Skin substitutes that received a 510(k) clearance, PMA approval, or a granted De Novo request will continue to be evaluated in the biannual HCPCS Level II coding cycles.

After careful consideration of the comments, we are finalizing our proposal to evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles as proposed.

If skin substitutes that are not licensed under section 351 of the PHS Act are no longer paid as biologicals using the methodology under section 1847A of the Act, as proposed, then the manufacturers of these products would no longer be required to report ASP data to CMS under section 1847A(f)(2) of the Act. However, as noted previously in this section, when ASP data is reported, it may serve as a better estimate of resources across the hospital outpatient and non-facility settings than hospital outpatient MUC data. We proposed to update the rates for the skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. However, we have concerns that using a single, scheduled quarter of ASP data to set payment rates could encourage gaming. We sought comments on the use of a longer timeframe, such as the most recently available four calendar quarters, to set payment rates in future years. In the event ASP is not available for a particular

product, we proposed using the MUC data. If MUC is not available, we proposed to use the product's WAC or 89.6 percent of AWP if WAC is also unavailable, similar to other products for which ASP is used to calculate a payment rate.[119] Once updated use patterns reflecting this policy are available to calculate rates, we proposed using all relevant products and the combined product utilization patterns (OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three categories. We sought comments on our proposed methodology to set and update the payment rates for skin substitutes as well as the rates themselves.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The most common recommendation was that CMS should update the payment rates annually using an inflation index, such as the Consumer Price Index for Urban Consumers (CPI-U) or the Producer Price Index (PPI), rather than recalculating them based on new ASP data. The commenters stated that an inflationary update would provide stability and predictability for providers and manufacturers, avoiding the significant rate variability that would occur with annual ASP recalculations, and reduce the regulatory burden on both manufacturers and CMS. Also, since the proposal would no longer require manufacturers to report ASP data for these products, commenters stated there would be very little reliable data to use for future updates. They stated that relying on ASP would perpetuate the same system that has been susceptible to gaming and abuse.

Several commenters recommended CMS to abandon any reliance on ASP data for setting future payment rates. They stated that the ASP system itself is flawed and has led to the pricing distortions and "profiteering" that CMS is trying to correct. Because the data is distorted, using it to set future rates—even if based on claims—will perpetuate the problem. In contrast, a commenter encouraged CMS to continue collecting ASP data for transparency and to support future reimbursement refinements, even if it is not the primary basis for payment.

Response: We appreciate the commenters for their input. We believe that, over time, the ASP data will more accurately reflect the market impacts of our policy to treat skin substitute products as incident-

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[119] 89.6 percent of AWP was calculated by first reducing the usual 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup.

to supplies. By relying on ASP, payment updates will be responsive to changes in the actual cost of skin substitute products as a result of market pressures, whereas an index like the CPI-U is a general inflation measure that does not account for pricing dynamics. Therefore, we believe that updating the payment rates based on ASP data will more likely result in payment rates that reflect the changing dynamics of the market rather than anchoring the cost to the initial payment rate for CY 2026 based on data collected prior to the implementation of this policy.

Comment: Several commenters expressed concern that using a single, scheduled quarter of ASP data for updates would encourage gaming. MedPAC recommended that if ASP data is used, it should be from a longer timeframe, such as 4 calendar quarters, to avoid manipulation.

Response: We agree that, moving forward, using a longer timeframe for collection of ASP data would reduce the opportunity for manipulation. While we may be unable to use a longer timeframe if we propose updated rates for 2027, we will look to additional quarters of data to set rates in future years.

Comment: Several commenters stated the proposal may violate the Administrative Procedure Act (5 U.S.C. 706(2)(A)), which requires well-reasoned analysis for major policy changes. A commenter stated the drastic reimbursement reduction constitutes a de facto adverse National Coverage Determination without following statutory NCD requirements: public notice, consultation with advisory committees, evidence consideration, and clear basis statements (42 U.S.C. 1395y(l)(3)-(4)).

Response: This rule finalizes a proposed change of *payment* policy. It neither constitutes nor is akin to a national coverage determination as it does not make any coverage determinations but merely makes a change to the amount of payment made for certain covered skin substitutes. Section 1869(f)(1)(B) (i.e., 42 U.S.C. 1395ff(f)(1)(B)) defines the term "national coverage determination" as "a determination by the Secretary for whether or not a particular item or service is covered nationally under this subchapter, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this subchapter or a determination with respect to the amount of payment made for a particular item or service so covered." The provision the commenters cite, 42 U.S.C. 1395y (section 1862 of the Act) expressly incorporates this definition of the term. See 42 U.S.C. 1395y(a)(25) (section 1862(a)(25) of the Act). Because this is not a "national coverage determination," the requirements set forth in 42 U.S.C. 1395y(l)(3)-(4) do not apply on their own terms.

Moreover, we believe our proposal satisfies the requirements of the Administrative Procedure Act and it is not arbitrary and capricious because we have, for example:

- Explicitly considered and responded to a dramatic increase in Medicare spending for this class of products,
- Provided a reasoned explanation for our classification of non-section 351 products as incident-to supplies rather than biologicals separately payable under section 1847A of the Act,
- Articulated our rationale for using OPPS utilization data and excluding non-facility utilization because of the profit-maximizing incentives distorting the latter,
- Explained the methodology for calculating the final payment rate with sufficient detail to allow verification by the public,
- Offered and analyzed several alternatives and explained why our final approach better serves statutory objectives,
- Acknowledged potential access concerns while reasonably concluding that a sufficient number of manufacturers have demonstrated the ability to provide these products at or below the final payment rate and assuring that we will monitor and adjust the policy in future rulemaking as necessary, and, finally,
- Described and responded to the comments CMS received in response to the proposed rule.

Several comments, including those related to coverage and the skin substitute LCDs and requests to change how the FDA regulates products CMS considers skin substitutes for payment purposes, were out of scope for purposes of this rulemaking.

5. Summary

To implement this policy, we are finalizing, starting January 1, 2026, to separately pay for covered skin substitute products as incident-to supplies in both the non-facility and hospital outpatient settings. We are finalizing our policy to create three groups to pay for covered sheet skin substitutes based on their FDA regulatory categories, PMA, 510(k), and 361 HCT/P, and would include each skin substitute in the applicable category based on its FDA approval, clearance, or self-determination. If a skin substitute is licensed under section 351 of the PHS Act, as described earlier in this section, the payment methodology under section 1847A would continue to apply. We are finalizing our policy to calculate

initial payment rates for covered skin substitute products in each of the three FDA regulatory categories using the volume-weighted average ASP for skin substitute products in each group as submitted by manufacturers, when available, and the MUC when ASP is not available. We are finalizing to use the hospital outpatient utilization patterns to set the payment rates for all three categories of skin substitutes, which we are finalizing to pay at a single rate for CY 2026. For CY 2026, the PE and MP RVUs would result in an initial payment rate of approximately \$127.28/cm^2 (prior to the application of the geographic adjustments) for PMA approvals, 510(k)s, and registered 361 HCT/Ps. This rate reflects updates to several code classifications and uses the most recent data available as of the time of drafting the proposed rule. We will accomplish this by maintaining the current HCPCS codes for skin substitutes and then applying this rate to each code. We are finalizing a policy to consider products that are not in sheet form to be skin substitutes for purposes of providing separate payment as incident-to supplies under this policy and to price these products by the MACs. We are finalizing to update the rates for the skin substitute categories annually through rulemaking using one or more recently available calendar quarter(s) of ASP data, when available. In the event ASP data is not available for a particular product, we are finalizing to use the hospital outpatient MUC data. If MUC is not available, we will use the product's WAC or 89.6 percent of AWP if WAC is also unavailable. We are finalizing to include all covered skin substitute products used across both settings as well as the combined product utilization patterns, as soon as data is available that reflects the results of this policy, to determine a weighted average per-unit cost by group to set the payment rates for each of the three categories. Additionally, we are finalizing the conversion of all skin substitute products codes to add-on codes with an indicator of ZZZ. We are finalizing our policy to evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles. Finally, we are finalizing our proposal to codify the definition of "biological" as "a product licensed under section 351 of the Public Health Service Act" at §§ 414.802 and 414.902.

L. Strategies for Improving Global Surgery Payment Accuracy

1. Background

CMS establishes valuation and payment for approximately several thousand physician services as "global surgical packages" (herein 'globals') under the PFS. Each package includes a surgical procedure defined by the HCPCS code as well as related services, for example, pre and immediate post-operative care on the day of the procedure, care related to complications, and discharge services, and post-operative evaluation and management (E/M) services typically provided during postoperative periods of specified lengths called "global periods." Currently, CMS pays for approximately 5,500 globals covering 0-, 10- and 90-day postoperative periods. Of the 5,500 total global surgical procedures, approximately 4,200 have either a 10- or 90-day global periods and nearly all of these 4,200 globals have at least one post-operative E/M visit included as part of their respective global surgical packages. Global surgical packages apply to the practitioner performing the procedure and, in the case of group practices, to the entire practice. Practitioners outside of those performing the procedure (or in the same group practice) can separately bill for post-operative and other care related to a global surgical procedure.

Taking into consideration findings from OIG reports that practitioners were performing fewer post-operative visits than Medicare assumed when valuing globals as well as our internal analysis, we finalized a policy in the CY 2015 PFS final rule (79 FR 67548) to transition all globals with 10-day and 90-day global periods to have 0-day global periods. This change would allow practitioners to bill separately for any post-operative visits (or other care related to the procedure, for example, care for complications) furnished after the day of the procedure to be billed as standalone services. However, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), prohibited CMS from implementing this finalized policy and required that we collect data on the number and level of post-operative visits provided to enrollees as part of global periods and use this information to improve the valuation of globals.

In response to the MACRA requirements, CMS developed a claims-based reporting system and required practitioners in nine states and in practices of 10 or more National Provider Identifiers (NPIs) to report post-operative visits falling with global periods using no-pay HCPCS code 99024. We also initiated a research contract with RAND to analyze the collected data, to conduct a survey-based study on

the level of post-operative visits, and to model different approaches to use the collected data and other information to improve the accuracy of valuation for global surgical services (see 81 FR 80212 through 80222 for more detailed discussion).

We recognize that, in some cases, a practitioner may only furnish the procedure component of a global surgical package, while in others, a practitioner may only provide post-operative care. In these cases, we rely on a set of transfer of care modifiers to split the fixed overall valuation of global surgical packages between providers. CMS broadened the scope for required reporting of transfer of care modifier -54 (*Surgical care only*) in the CY 2025 PFS Final Rule as part of an iterative process to improve global package valuation and therefore payment. Previously, this modifier could only be attached to global procedures with a 10 or 90-day global period when a patient's transfer of care was formally documented by both the surgeon and one or more post-operative care practitioners. In internal analyses, CMS found modifier -54 was used only rarely in aggregate and was concentrated in a small number of ophthalmologic and cardiology procedures. Beginning January 1, 2025, and onward, modifier -54 must be reported in all cases where the surgeon does not intend to provide post-operative care, including but not limited to cases where both the surgeon and another practitioner both formally document the transfer of care as under the previous policy (see 89 FR 97961 through 97967 for that discussion).

For CY 2025, we also finalized a new add-on code, HCPCS code G0559, for post-operative care services furnished by a practitioner other than the one who performed the surgical procedure (or another practitioner in the same group practice). This add-on code will more appropriately reflect the time and resources involved in these post-operative follow-up visits by practitioners who were not involved in furnishing the surgical procedure however may see the patient for postoperative care (see 89 FR 97968 through 97971 for that discussion).

2. Strategies to Address Global Package Valuation

We noted in the CY 2025 PFS final rule that our proposal to broaden the required use of the transfer of care modifiers was a first step in an iterative process towards improving the accuracy of global surgical service valuation and payment. We are considering the next steps to improve the valuation and payment for these services. We are continuing to consider approaches to establishing the payment allocations for portions of the global package when the transfer of care modifiers is used. Furthermore, we

are considering approaches to specifically use information reported to CMS on the number and level of post operative visits to improve global surgical service valuation as required by section 1848(c)(8)(C) of the Act.

We requested comments in the CY 2025 PFS proposed rule (89 FR 61596) on how best to determine the appropriate shares used to split total global surgical package valuations into discrete portions for the purpose of determining valuation (and therefore payment) in transfer of care scenarios. We sought comment on potential approaches to revise these shares and how they could better reflect current medical practice and conventions for post-operative follow-up care. We sought to identify a procedure-specific, data-driven method for assigning shares to portions of the global package valuation to more appropriately align the resources involved in each portion to payment rates. We stated in the CY 2025 PFS proposed rule that we would appreciate and carefully consider recommendations from interested parties, including the AMA RUC, on what those shares should be and other relevant information. We also stated in the proposed rule that CMS could use data collected over nearly a decade on the observed number of post-operative visits furnished to patients as part of global surgical packages as the basis for calculating new data-driven shares. We note that we received few comments in response to our comment solicitation.

Currently, Medicare pays surgeons a fixed share of a global procedure's valuation when billed with specified modifiers, specifically, modifier -54. These "procedure shares" are based on long-standing assumption and are clustered at certain values, for example, 79 percent, 80 percent, or 81 percent for roughly half of procedures with 90-day global periods and 90 percent for most procedures with 10-day global periods (the remaining approximately 20 percent and 10 percent for 90-day and 10-day procedures, respectively, account for post-operative care). We believe that the use of these distinct portions of the global package will help us to best align valuation—and therefore payment—to the practitioner who is performing a specific portion of the global surgical service.

We received feedback from commenters that the current component percentages published in the PFS were developed using magnitude estimation and cross-specialty scaling and that there is not any reverse engineering of work and time that can be performed to develop a better percentage of pre-, intra- and post-operative work than what is currently published in the PFS. Given the fact that both PFS global

surgical procedures and relative valuations have changed since the inception of the PFS, we believe there may be better ways to provide the correct apportionments to the global surgical packages. Furthermore, clinical practice, including post-operative care that has changed dramatically over the decades since the inception of the current shares. We did not update procedure shares in the CY 2025 PFS final rule.

We again solicited public comments on strategies to improve the accuracy of payment for global surgical packages, specifically related to the procedure shares. We sought public comments on what the procedure shares should be based on for the 90-day global packages. We also sought comments and stakeholder input as to current practice standards and division of work between surgeons and providers of post-operative care. Currently, there is no clear basis for the current procedure shares, and this will allow for stakeholder input as to what those procedure shares should be.

We received public comments on this comment solicitation. After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

In accordance with MACRA, we have been collecting data on post-operative visits furnished as part of global surgical packages and the extent to which these furnished post-operative visits align with the number of post-operative visits assumed by CMS when valuing global surgical services. For procedures with 90-day global periods and 2023 dates of service, our internal analysis shows that only 28 percent of post-operative visits considered by CMS during global surgical service valuation were actually provided to enrollees as part of global surgical packages. Our internal findings and RAND's published analyses have consistently shown that only a fraction of "expected" post-operative visits are provided. Absent evidence to the contrary, which CMS has not identified despite several solicitations for comments from the public (89 FR 97961 through 97962), our interpretation is that many post-operative visits considered during the valuation of global surgical packages are not provided as part of these packages. This presents an opportunity to use information from claims-based reporting of post-operative visits to develop procedure shares that better reflect current practice patterns. Using this data, as established through notice and comment rulemaking (81 FR 80212 through 80222), we considered several options regarding how the procedure shares could be updated, based on the data that was analyzed. These options are available in the file titled "Estimated Procedure Shares Under Procedure-Only Modifier -54, Surgical

Services with 90-day Global Period" on the CMS website under downloads for the CY 2026 PFS final rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

As we continue to contemplate how to pay more accurately for global surgical packages, and specifically in consideration of how the procedure shares could be updated, we identified three alternatives to the status quo assumed procedure shares (that is, the share of a global surgical package valuation assigned to the surgeon when modifier -54 is reported) for global surgical packages. Each alternative uses information available in claims data to calculate new HCPCS code-specific procedure shares. Each alternative also calculates procedure shares as the ratio of procedure work RVUs (defined as the sum of intraservice work and other work on the day of the procedure (that is, pre-service work) as indicated on the Physician Time File to total global surgical package work RVUs. The Physician Time File and Addendum B are both located under the Download files for this proposed rule at: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices. The approaches differ in the way we would calculate procedure work RVUs, and more specifically, intraservice work as a component of procedure work RVUs.

Under the first approach, we would calculate procedure work RVUs by subtracting work RVUs assigned to each post-operative visit listed in the Physician Time File for a global procedure HCPCS code from the total valuation of the global surgical package. Under the second approach, we would calculate procedures' work RVUs by subtracting the work RVUs for post-operative visits provided as part of global surgical packages. To do so, we would multiply the number of post-operative visits typically provided for the global procedure HCPCS code (defined as the median count of post-operative visits reported to CMS using no-pay code 99024 among procedures without overlapping global periods with other global surgical services) by the average valuation per post-operative visit calculated for the mix (that is, number and level) of post-operative visits for the global procedure HCPCS code as listed in the Physician Time File. Under the third approach, would calculate procedure RVUs as the product of total physician time (in minutes) for each global procedure HCPCS code from the Physician Time File and the ratio of physician time (in minutes) assigned to post-operative visits for the code in the Physician Time File to total physician time.

In the CY 2025 PFS final rule, we expanded the scope for modifier -54 (surgical care only) to include all scenarios where the surgeon does not expect to provide post-operative care. The scope for modifier -55 (post-operative care only) was not changed. As a result, the post-operative share of total global surgical package valuation can only be billed with modifier -55 when transfers of care are formally documented by the surgeon and another practitioner.

Looking at 2023 claims data, RAND's analyses suggest the current procedure shares do not reflect the real-world division of work between surgeons and providers of post-operative care. Across all CY 2023 90-day global procedures and weighted by procedure volume, the procedure share under our current assumed procedure shares would have been 82 percent, on average, assuming all procedures were billed with modifier -54. Under the procedure shares calculated based on the actual number of visits furnished in global surgical periods (determined using information from claims-based reporting of post-operative visits), the average procedure share would have been 91 percent, with 85 percent of procedures having higher procedure shares under this approach compared to CMS' current assumptions.

We sought comments on the best approach to utilize going forward, specifically on the CPT code 99024-based approach. Of these approaches, the first (in terms of work RVUs) and third (in terms of physician time minutes) rely on Physician Time File counts of the number and level of post-operative visits assumed to occur as part of global surgical packages. Based on prior analyses (see 89 FR 97961), these counts are substantially inflated. Of all Physician Time File assumed visits and for 2023 global surgical procedure volumes, only 2 percent of visits following procedures with 10-day global periods and 28 percent of visits following procedures with 90-day global periods were provided to patients as part of global surgical packages. For this reason, we believe the resulting procedure shares under these approaches are too low and would lead to payments to surgeons that do not reflect the time and resources involved in furnishing the procedure component of global surgical services. In contrast, the second approach (using post-operative visit counts from claims-based reporting) reflects real-world, observed patterns of post-operative care. Furthermore, the second approach allows for routine, transparent updating of procedure shares over time. In contrast, shares could be updated under the first and third approaches only when global surgical services are revalued, and even then, with the limitation noted previously that the resulting visit counts by E/M service level are often substantially too high.

We sought comments on replacing the current procedure shares using the second approach described previously (that is, with procedure work RVUs calculated using counts of post-operative visits reported using no-pay CPT code 99024).

Additionally, in our internal review of the percentages assigned for the pre-operative, surgical care, and post-operative portions of the global packages, we found that there are a small number of codes that do not have any assigned percentages in our files even though these codes are identified as global packages. We sought comments again on whether we should consider, first, whether these codes are appropriately categorized as 90-day global package codes, and if so, we sought comments on what the assigned percentages should be for each portion of the service.

We received public comments on this comment solicitation. After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

M. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: work, practice expense (PE), and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource-based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary, adjust RVUs no less often than every 5 years. As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor (RF) was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) specialty-level risk values derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk values derived from Medicare claims data of the weighted average risk values of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk value based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we discussed this methodology and finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the three most recent years of data instead of a single year of data. Under this approach, for

new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding the specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data but would remain unchanged between the 5-year reviews.

In the CY 2018 PFS proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors used in the calculation of MP RVUs prior to the next required 5-year update (CY 2020) using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however, the proposal was ultimately not finalized for CY 2018.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. In the CY 2020 PFS final rule (84 FR 62606 through 62615), we implemented the fourth review and update of MP RVUs, and we also conducted the statutorily required 3-year review of the GPCIs. The MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Therefore, to increase efficiency, we finalized a policy to align the update of MP premium data and specialty-level risk factors with the update to the MP GPCIs. We finalized a policy to review, and if necessary, update the MP RVUs at least every 3 years, similar to our review and update of the GPCIs.

In the CY 2023 PFS final rule, we conducted the statutorily required review of the MP RVUs and GPCIs (87 FR 69634 through 69641). We refer to this review and update of the MP RVUs as the "CY 2023 update." As part of this review, we finalized a methodological improvement to move from MP risk factors to a MP risk index. The risk index is calculated as a ratio of the specialty's national average premium to the volume-weighted national average premium across all specialties. We finalized this methodological improvement to increase consistency with the calculation of MP RVUs, so that changes in the MP risk index reflect changes in payment, as opposed to changes relative only to the specialty with the lowest national average premium.

2. Methodology for the Revision of Resource-based Malpractice (MP) RVUs

a. General Discussion

We calculated the MP RVUs that we proposed for CY 2026 using updated MP premium data obtained from state insurance rate filings. The methodology used to calculate the CY 2026 resource-based MP RVUs largely parallels the process used in the CY 2023 update with continued improvements to our data collection process. To calculate the MP RVUs, we obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk values for the various specialties that furnish a particular service. Because MP premiums vary by state and specialty, we weigh the MP premium data geographically and by specialty. We calculated the MP RVUs we proposed using four data sources: data on MP insurance premium rates presumed to be in effect as of December 31, 2023; CY 2023 Medicare payment and utilization data; higher of the CY 2025 final work RVUs or the clinical labor portion of the direct PE RVUs; and CY 2025 GPCIs. We used the higher of the CY 2025 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2026 proposed MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2023 update, we calculated the proposed MP RVUs using specialty-specific MP premium data because they represent the expense incurred by practitioners to obtain MP insurance as reported by insurers. For CY 2026, we obtained the most current MP insurance premium data available, reflecting rates with a presumed effective date of no later than December 31, 2023, from insurers with the largest market share in each state. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) 2023 market share report. This annual report provides State-level market share for entities that provide premium liability insurance (PLI) in a state. Premium data was downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating States. For non-SERFF States, data was downloaded from the State-specific website (if available online) or obtained directly from the State's alternate access to filings. For SERFF States and non-SERFF States with online access to filings, we used the 2023 market share report to select insurance companies. These market share filings were the most current data available during the data collection and acquisition process.

MP insurance premium data was collected from all 50 States and the District of Columbia. We made efforts to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection, and therefore, we used filings from the previous update. Consistent with the CY 2023 MP

RVU update, we did not collect filings for the other U.S. territories: American Samoa, Guam, Virgin Islands, or Northern Mariana Islands. We collected MP insurance premium data for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. We made adjustments to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the state's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

In the CY 2020 PFS final rule (84 FR 62607 through 62610), we finalized methodological improvements that expanded the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs. Premium data were included for all physician and nonphysician practitioner (NPP) specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all States, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all States.

b. Methodological Refinements

For the CY 2026 update, we did not propose any major methodological refinements to the development of MP premium data. However, we have continued to refine the universe of specialties subject to imputation and sources of imputation for each specialty. For the CY 2023 update, premium data for the specialties of Geriatric Medicine, Hospitalist, Internal Medicine, Medical Oncology, Pain Management, and Preventive Medicine were augmented with some imputed data, but sufficient data was collected for these specialties during this CY 2026 update such that imputation was unnecessary. Additionally, Allergy/Immunology was previously used as the imputation source for both Osteopathic Manipulative Medicine and Addiction Medicine. For this CY 2026 update, more clinically similar specialties were used as the imputation source for these specialties.

c. Steps for Calculating Malpractice RVUs

Calculation of the MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 PFS final rule with comment period (79 FR 67591), along with the methodological improvements established in the CY 2023 PFS final rule (87 FR 69634 through 69641). The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk index of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area MP premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2018 to 2022 American Community Survey (ACS) 5-year estimates). This contrasts with the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the 2025 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of MP claims if they occur. To account for the presence of different classes in the MP premium data and the task of mapping these premiums to procedures, we calculated a distinct risk index for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data

by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several methods for calculating average premiums by specialty.

Developing Distinct Service Risk Groups: We determined that there was sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 17 specialties. These specialties are listed in Table A-M1. The CY 2026 update uses the same structure of specialty/service risk group as the CY 2023 update. For all other specialties (those that are not listed in Table A-M1) that typically do not distinguish premiums as previously described, a single risk index value was calculated, and that specialty risk index value was applied to all services performed by those specialties.

TABLE A-M1: SPECIALTIES SUBDIVIDED INTO SERVICE RISK GROUPS

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Cardiac Electrophysiology (21), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93) Unknown Physician Specialty (99)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Step (3): Calculate a risk index for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk index. These risk index values are calculated by dividing the national average premium for each specialty by the volume-weighted national average premium across all specialties. Risk index values less than one correspond to specialties with relatively lower malpractice risk than average, and values greater than one correspond to specialties with relatively higher malpractice risk. The volume-weighted national average premium was calculated as the sum of the product of the national average premium and total CY 2023 PE and work RVUs for each specialty/service risk group, then dividing by total CY 2023 PE and work RVUs across all specialties.

(a) Technical Component (TC) Only Services

For the CY 2020 update of the MP RVUs (84 FR 62606 through 62615), we finalized that we would assign a risk factor of 1.00, which was the lowest physician specialty risk factor (allergy/immunology), to TC-only services due to a lack of sufficient professional liability premium data. For the proposed CY 2023 update of the MP RVUs (87 FR 46016), our expanded data collection efforts

resulted in sufficient premium data such that we could directly assign a risk value for TC- only services without the need for mapping. However, due to a technical error, we continued to assign a 1.0 risk factor for all TC-only services which resulted in an incorrect calculation of the proposed MP RVUs for TC-only services. In the CY 2023 PFS final rule (87 FR 69641), we finalized a correction to this ratesetting error for the 2023 update of the MP RVUs that again mapped TC-only services to allergy/immunology, which had a risk index value of 0.430. We stated that using this risk value will correct the identified error, while also maintaining as much stability as possible for TC-only services so that there is not a major shift in value from current MP RVUs for the technical and professional components.

For this CY 2026 update of the MP RVUs, we are proposing to map TC-only services to the specialty allergy/immunology, which now has a risk index value of 0.427. Mapping the TC-only services to the specialty allergy/immunology would be consistent with the CY 2020 and 2023 updates of the MP RVUs and maintain stability in our ratesetting process. We requested comments regarding the risk index value for TC-only services. Table A-M2 shows the risk index values by specialty type and service risk group.

TABLE A-M2: CY 2026 Risk Index by Specialty and Service Risk Group

Medicare Specialty Code and Name	2026 Service Risk Group	2026 Risk Index
01-General practice	NO SURG	0.723
01-General practice	SURG	1.438
01-General practice	OB	1.706
02-General surgery	ALL	3.074
03-Allergy/immunology	ALL	0.427
04-Otolaryngology	NO SURG	0.711
04-Otolaryngology	SURG	1.679
05-Anesthesiology	ALL	0.967
06-Cardiology	NO SURG	0.815
06-Cardiology	SURG	2.754
07-Dermatology	NO SURG	0.492
07-Dermatology	SURG	1.135
08-Family practice	NO SURG	0.726
08-Family practice	SURG	1.494
08-Family practice	OB	1.716
09-Interventional Pain Management	ALL	1.189
10-Gastroenterology	NO SURG	0.867
10-Gastroenterology	SURG	1.290
11-Internal medicine	ALL	0.793
12-Osteopathic manipulative medicine	ALL	0.590
13-Neurology	NO SURG	0.968
13-Neurology	SURG	4.845
14-Neurosurgery	ALL	4.845
15-Speech Language Pathology	ALL	0.012
16-Obstetrics/gynecology	NO SURG	0.992
16-Obstetrics/gynecology	SURG	2.017

Medicare Specialty Code and Name	2026 Service Risk Group	2026 Risk Index
16-Obstetrics/gynecology	OB	3.686
17-Hospice & Palliative Care	ALL	0.780
18-Ophthalmology	NO SURG	0.505
18-Ophthalmology	SURG	0.918
19-Oral surgery (dental only)	ALL	1.313
20-Orthopedic surgery	ALL	2.451
21-Cardiac Electrophysiology	NO SURG	0.815
21-Cardiac Electrophysiology	SURG	2.763
22-Pathology	ALL	0.655
23-Sports Medicine	ALL	0.740
24-Plastic and reconstructive surgery	ALL	2.136
25-Physical medicine and rehabilitation	ALL	0.600
26-Psychiatry	ALL	0.475
27-Geriatric Psychiatry	ALL	0.475
28-Colorectal surgery	ALL	1.657
29-Pulmonary disease	ALL	0.971
30-Diagnostic radiology	ALL	1.099
31-Intensive Cardiac Rehab	ALL	0.815
32-Anesthesiologist assistants	ALL	0.264
33-Thoracic surgery	ALL	2.895
34-Urology	NO SURG	0.830
34-Urology	SURG	1.480
35-Chiropractic	ALL	0.154
36-Nuclear medicine	ALL	0.602
37-Pediatric medicine	ALL	0.705
38-Geriatric medicine	NO SURG	0.682
38-Geriatric medicine	SURG	1.649
39-Nephrology	NO SURG	0.713
39-Nephrology	SURG	1.143
40-Hand surgery	ALL	1.964
41-Optometry	ALL	0.046
42-Certified nurse midwife	ALL	1.021
43-CRNA	ALL	0.269
44-Infectious disease	ALL	0.910
45-Mammography screening center	ALL	0.016
46-Endocrinology	NO SURG	0.770
46-Endocrinology	SURG	1.430
47-Independent Diagnostic Testing Facility	ALL	0.016
48-Podiatry	NO SURG	0.452
48-Podiatry	SURG	0.982
62-Psychologist	ALL	0.064
63-Portable X-ray supplier	ALL	0.014
64-Audiologist	ALL	0.015
65-Physical therapist	ALL	0.034
66-Rheumatology	ALL	0.674
67-Occupational therapist	ALL	0.024
68-Clinical psychologist	ALL	0.064
69-Clinical laboratory	ALL	0.016
70-Multispecialty clinic or group practice	ALL	0.714
71-Registered Dietician/Nutrition Professional	ALL	0.192
72-Pain management	ALL	1.128
75-Slide Preparation Facilities	ALL	0.016
76-Peripheral vascular disease	ALL	2.937
77-Vascular surgery	ALL	2.937
78-Cardiac surgery	ALL	2.754
79-Addiction medicine	ALL	0.484
80-Licensed clinical social worker	ALL	0.022
81-Critical care (intensivists)	ALL	1.200

Medicare Specialty Code and Name	2026 Service Risk Group	2026 Risk Index
82-Hematology	ALL	0.750
83-Hematology/oncology	ALL	0.782
84-Preventive medicine	ALL	0.544
85-Maxillofacial surgery	ALL	1.670
86-Neuropsychiatry	ALL	0.475
90-Medical oncology	ALL	0.746
91-Surgical oncology	ALL	2.664
92-Radiation oncology	ALL	0.918
93-Emergency medicine	NO SURG	1.478
93-Emergency medicine	SURG	2.854
94-Interventional radiology	ALL	1.501
98-Gynecologist/oncologist	ALL	2.664
99-Unknown physician specialty	NO SURG	0.714
99-Unknown physician specialty	SURG	1.229
C0-Sleep Medicine	ALL	0.909
C3-Interventional Cardiology	ALL	2.724
C6-Hospitalist	ALL	0.940
C7-Advanced Heart Failure & Transplant Cardiology	ALL	0.815
C8-Medical toxicology	ALL	1.478
C9-Hematopoietic cell transplantation and cellular therapy	ALL	0.799
E1-Marriage and family therapist (MFT)*	ALL	0.022
E2-Mental health counselor (MHC)*	ALL	0.022
E3-Dental anesthesiology*	ALL	0.954
E6-Oral and maxillofacial pathology*	ALL	0.609
E7-Oral and maxillofacial radiology*	ALL	1.083
F1-Orofacial pain*	ALL	1.121

*Note: CMS specialty codes denoted with an asterisk (*) were established for billing purposes effective January 1, 2024. This is the first update for which risk index values have been calculated for these specialties.

Step (4): Calculate MP RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This percentage was then multiplied by each respective specialty's risk index value as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk index reflecting the weighted MP costs across all specialties furnishing that procedure. The service specific risk index was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

For low volume services codes, we finalized in the CY 2018 PFS final rule (82 FR 53000 through 53006) a proposal to apply the list of expected specialties instead of the claims-based specialty mix for low volume services to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services (which also includes no volume services); these are defined as codes that

have 100 allowed services or fewer. These service-level overrides are used to determine the specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2026, we solicited public comment on the list of expected specialties. The list of codes and expected specialties is available on our website under downloads for the CY 2026 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We received public comments on the list of expected specialties. The following is a summary of the comments we received and our responses.

Comment: Commenters recommended some additional CPT codes to be added to the *CY 2026 PFS Proposed Rule Anticipated Specialty Assignment for Low Volume Services* list[120].

Response: We appreciate commenters' suggested additions of low volume services CPT codes to the CY 2026 PFS Proposed Rule Anticipated Specialty Assignment for Low Volume Services list. We refer readers to the PE RVU Methodology section of this final rule for a discussion regarding the list and the suggested additions for CY 2026.

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource-based MP RVUs are equal to the total current resource-based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for

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[120] https://www.cms.gov/files/zip/cy-2026-pfs-proposed-rule-anticipated-specialty-assignment-low-volume-services.zip.

individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we discuss specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We proposed to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We note that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we proposed to also exclude for the purpose of calculating MP RVUs is available in section II.B. of this final rule, Determination of Practice Expense Relative Value Units. The resource-based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2026 PFS rule at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work currently represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type are detailed in section VII. of this final rule, the Regulatory Impact Analysis.

Additional information on our methodology for updating the MP RVUs is available in the "Interim Report for the CY 2026 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule," which is available on the CMS website under the downloads section of the CY 2026 PFS final rule at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the 2026 update to the risk index values used in the calculation of the MP RVUs. They commend CMS' continued work to expand data collection efforts by collecting as much specialty-specific data as possible to reflect the most accurate trends in malpractice premiums. Commenters requested that CMS continue to use more specialty-specific data not subject to imputation as well as increased transparency in the overall MP RVU update methodology.

Response: We appreciate the commenters for their feedback and support. We will continue to expand our data collection efforts for future updates of the Malpractice Risk Index. For an in-depth analysis and transparency of the MP RVU update process, we remind commenters of the interim and final reports referenced earlier in this section of the rule that outlines all steps of the update process and data imputation methodologies.

Comment: Commenters requested that CMS revisit their 2016 policy regarding exemptions for add-on codes and establish a minimum floor for MP RVUs where the practicing specialty's RVUs are significantly low. Commenters stated this would prevent a 0 MP RVU value for specialties that have a low, but still measurable, malpractice risk.

Response: For the CY 2026 PFS proposed rule, we did not make any proposals regarding our policy to implement an MP RVU floor of 0.01 with an exemption for add-on codes, as finalized in the CY 2016 PFS final rule (80 FR 70908). We direct readers to the CY 2016 PFS final rule (80 FR 70908) for further discussion on this exemption for add-on codes and we may consider modifications to this policy for future rulemaking.

Comment: A commenter suggested that CMS make changes to the specialty premium data source for a few specialties that they believe are incorrectly mapped for the purposes of data imputation. The commenter also noted that they believe CMS could improve the imputation methodology by publishing impacts for all CMS specialties instead of mapping to related specialties in the regulatory impact table included in all PFS **Federal Register** notices. Additionally, the commenter stated that they would like CMS to work with the RUC to better identify appropriate crosswalks when necessary. The commenter's requested changes to mappings used in data imputation are as follows: 72-Pain Management to 11-Internal Medicine, 98-Gynecologist/oncologist to 91-Surgical oncology, C0-Sleep Medicine to 13-Neurology, and 85- Maxillofacial surgery (ALL) to 04-Otolaryngology (SURG).

Response: We appreciate the commenter's revised mapping suggestions for some specialties that require imputation of premium data. We also note that we will continue to work with all interested parties to improve the data used for calculating risk index values. We continue to believe that the list of CMS specialties contained in the regulatory impact table (Table 92 CY 2026 PFS Estimated Impact on Total Allowed Charges by Specialty) (90 FR 32803) is a useful tool to assist with mapping premium data when specialty -specific premium data are not included in a filing. However, as we previously discussed in this rule, we have adopted policies to improve our data imputation and employ partial imputation based on available data to approximate the premiums when we do not have complete specialty -specific premium data, as reflected in Table 8.C (Source Specialty/Service Risk Group for Imputation for Updated PLI Premium Data) of the interim report "CY2026 Medicare Physician Fee Schedule (PFS) Update to the Geographic Practice Cost Indices (GPCIs) and Malpractice (MP) Risk Index". For the suggested mapping of 72-Pain Management to 11-Internal Medicine , we disagree with the commenters, because for the 2026 update of the MP risk index values for 72-Pain Management, we were able to collect sufficient premium data such that data imputation was not required and we were therefore able to use the actual premium data to formulate a risk index value for this specialty. For the suggested mappings of 98-Gynecologist/oncologist to 91-Surgical oncology and C0-Sleep Medicine to 13-Neurology, we also disagree with the commenter and believe this comment was an error. 98-Gynecologist/oncologist is already mapped to 91-Surgical oncology and C0-Sleep Medicine is already mapped to 13-Neurology. We made these mapping changes for the last update of the MP Risk Index values in the CY 2023 PFS final rule (87 FR 69641) and continued with the mappings for the CY 2026 update. Lastly, for the suggested mapping of 85- Maxillofacial surgery (ALL) to 04-Otolaryngology (SURG), after further consideration and review of the commenter's request, we are finalizing a change for these specialties for the purposes of data imputation to reflect that 85- Maxillofacial surgery (ALL) is now mapped to 04-Otolaryngology (SURG).

After consideration of public comments, we are finalizing the CY 2026 update as proposed with a modification to one specialty mapping used in data imputation as described previously.

N. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS later in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in Frontier States (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which has been extended by many successive amendments to the statute. The 1.0 floor for the work GPCI under section 1848(e)(1)(E) of the Act was most recently extended by section 2206 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119-4, enacted March 15, 2025) through September 30, 2025 (that is, for services furnished no later than September 30, 2025). Therefore, the proposed CY 2026 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for Frontier States are permanent, and therefore, are reflected in the CY 2026 proposed GPCIs.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be one-half of the adjustment that otherwise would be made. Therefore, since more than 1 year has passed since the previous GPCI update was implemented in CY 2023 and 2024, we proposed to phase in one-half of the proposed GPCI adjustment in CY 2026 and the remaining one-half of the adjustment for CY 2027.

We have completed our review of the GPCIs and are finalizing new GPCIs beginning for CY 2026 in this final rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS locality's proposed work, PE, and MP GPCIs using the share of total RVUs that each component accounts for in the actual Medicare utilization from CY 2023. While we do not actually use GAFs in computing the PFS payment for a specific service, they are a useful metric for purposes of comparing overall costs and payments across fee schedule areas. The actual effect of GPCIs on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those reflected in the GAF.

See Addenda D and E to this proposed rule for the CY 2026 proposed GPCIs and summarized GAFs. These Addenda are available on the CMS website under the downloads section of the CY 2026 PFS final rule at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89 and increased the number of Statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113-93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23

additional localities, increasing the total number of PFS localities from 89 to 112. Subsequently, we operationalized a technical refinement to retire several California localities that were no longer operationally necessary, resulting in a reduction of unique California localities from 32 to 29 from CY 2024 on. We refer readers to the discussion of this technical refinement in the CY 2023 (87 FR 69621 through 69625) and 2024 (88 FR 78985 through 78987) PFS final rules, and the section below. As a result, the current 109 payment localities include 34 Statewide areas (that is, only one locality for the entire State) and 72 localities in the other 16 States, with 10 States having two localities, two States having three localities, one State having four localities, and three States having five or more localities. The remainder of the 109 PFS payment localities are comprised as follows: the combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We noted that the localities generally represent a grouping of one or more constituent counties.

The current 109 fee schedule areas, also referred to as payment localities, are defined alternatively by State boundaries (Statewide areas for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate geographically adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a State. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). The changes to the proposed CY 2026 GPCIs for each locality reflect the updated resource cost data in each area to better adjust PFS payments for geographic cost differences compared to

national average costs. We noted that the changes in the proposed GPCIs reflect the statutory floors and limitations on variation previously discussed that may advantage some rural localities. We describe the data sources and methodologies we use to calculate each of the three GPCIs later in this section. Additional information on the CY 2026 GPCI update is available in an interim report, "Interim Report for the CY 2026 Update of GPCIs and MP RVUs for the Medicare PFS," on our website located under the downloads section for the CY 2026 PFS final rule at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for nine professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated, and wage and earnings data were not available from the more recent Census because the "long form" was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), formerly known as Occupational Employee Statistics (OES), wage data as a replacement for the 2000 Census data. The BLS OEWS data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OEWS wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every

metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OEWS is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OEWS data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs; for the CY 2017 GPCI update, we used updated BLS OEWS data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs; for the CY 2020 GPCI update, we used updated BLS OEWS data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs; and for the CY 2023 GPCI update, we used updated BLS OEWS data (2017 through 2020) as a replacement for the 2014 through 2017 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OEWS data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed later in this section, the employee wage component and purchased services component of the PE GPCI). Therefore, for the CY 2026 GPCI update, we used updated BLS OEWS data (2020 through 2023) as a replacement for the 2017 through 2020 data to compute the proposed work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost

of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2023), we used 2017 through 2020 BLS OEWS data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OEWS is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the CY 2026 GPCI update, we used updated BLS OEWS data (2020 through 2023) as a replacement for the 2017 through 2020 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI. In calculating the CY 2026 GPCI update for the office rent index component of the PE GPCI, we used the 2018 through 2022 American Community Survey (ACS) 5-year estimates as a replacement for the 2015 through 2019 ACS data.

c. Malpractice Expense (MP) GPCIs

The Malpractice Expense (MP) GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). To ensure that premium data are homogenous and comparable across geographic areas, data were collected for policies with uniform coverage limits of $1 million per occurrence and $3 million aggregate ($1 million/$3 million). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million/$3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2023 GPCI update, we used premium data presumed in effect as of December 31, 2020. The CY 2026 MP GPCI update reflects premium data presumed in effect no later than December 31, 2023. We noted that

we finalized a few technical refinements to the MP GPCI methodology in CY 2017 and refer readers to the CY 2017 (81 FR 80270) PFS final rule for additional discussion of those.

d. GPCI Cost Share Weights

For the CY 2026 GPCIs, we proposed to continue to use the current 2006-based MEI cost share weights for determining the proposed PE GPCI values. Specifically, we use the cost share weights to weight the four components of the PE GPCI: employee compensation, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses, as shown in Table 31. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017, CY 2020, and CY 2023 GPCI updates.

We note that we proposed and finalized to rebase and revise the MEI cost share weights for CY 2023, and we refer readers to the detailed discussion in section II.M. of the CY 2023 PFS final rule (87 FR 69688 through 69710). Due to the concurrent rebasing and revision of the MEI cost share weights during the CY 2023 GPCI update, we proposed and finalized to maintain the use of the 2006-based MEI cost share weights for the CY 2023 GPCIs, thus delaying the implementation of the rebased and revised 2017-based MEI cost share weights for this purpose. We refer readers to our discussion about using the rebased and revised MEI cost share weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and for the purposes of updating the GPCIs in the CY 2023 PFS final rule (87 FR 69414 through 69415, 69619 through 69620, and 70212 through 70218). In those sections, we discussed our considerations for updating the MEI cost share weights for the RVUs and the GPCIs and the potential redistributive impact that making such a change would have had on PFS payments. We have historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI, which was most recently done for CY 2023. However, in light of the overall impacts of making this change and in the interest of maintaining stability in payments, we proposed and finalized to maintain the use of the currently used 2006-based MEI cost share weights for the CY 2023 final PE GPCIs. For the CY 2026 GPCI update, we have the same concerns about the potential redistributive effects that implementing the 2017-based MEI would have on PFS payments. Additionally, we have received data

from the American Medical Association's (AMA) Physician Practice Information[121] (PPI) and Clinician Practice Information[122] (CPI) Surveys, however, these data lack the specific breakdown of practice expense that we would need to consider its use to weight the four components of the PE GPCI for CY 2026, including Office Rent and Purchased Services, which are reported in an aggregate buckets of general overhead costs and other expenses in the survey data. We refer readers to section VII. of this final rule for more discussion regarding a possible derivation of cost share weights for use in the PE GPCI from the PPI and CPI Survey.

We also note that maintaining the 2006-based MEI cost share weights for the CY 2026 GPCI update preserves consistency in the data used to update both the GPCI and PFS ratesetting inputs for CY 2026. We refer readers to section VII. of this final rule for additional discussion on this issue and the estimated impacts as it relates to PFS ratesetting and the GPCI update for CY 2026. We also refer readers to the discussion regarding the PPI and CPI survey data in section II.B. of this final rule. In addition, we direct readers to the CY 2011 PFS final rule (75 FR 73256) where we similarly delayed implementation of updated MEI cost share weights in response to commenters' concerns about our separate, ongoing analysis that would inform future GPCI changes and the reallocation of labor-related costs from the medical equipment and supplies and miscellaneous component to the employee compensation component of the PE GPCI.

In the CY 2011 PFS final rule (75 FR 73256), we acknowledged that we typically update the GPCI cost share weights concurrently with the most recent MEI rebasing and revision, but in consideration of the commenters' concerns in response to the proposed rule, we did not use the revised cost share weights for the CY 2011 GPCIs and instead finalized the implementation of the rebased and revised MEI cost share weights through subsequent rulemaking. We sought comments on the 2017-based MEI cost share weights and the weights based on PPI and CPI Survey data for purposes of alternatives considered for the CY 2026 GPCIs and PFS ratesetting, given the estimated impacts discussed in section VII. of this final rule. We also sought comments on how best to proceed with implementation of the 2017-based MEI cost share weights or PPI and CPI Survey weights in the future. More specifically, we

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[121] https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.
[122] https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.

sought comment on how best to incorporate updated cost share weights into the PE GPCI if we were to implement them outside the statutorily required triennial update in which we phase in all aspects of the GPCI update through the previously discussed 2-year (one-half in each year) phase-in required by section 1848(e)(1)(C) of the Act. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be one-half of the adjustment that otherwise would be made. Therefore, we sought comment on potentially incorporating the updated cost share weights into the CY 2027 GPCIs. We note that we would not be required by statute to phase in the adjustment over 2 years as specified in section 1848(e)(1)(C) of the Act because, in CY 2027, no more than 1 year would have elapsed since this CY 2026 GPCI adjustment. Therefore, we also sought comment on whether it would be appropriate to use a multi-year transition to incorporate updated cost share weights for purposes of the PE GPCI and PFS ratesetting as we have done in the past when incorporating other new data into the PFS payment methodology (for example, the clinical labor update), or if, because updated cost share weights only impact the composition of the PE GPCI, such a transition would not be warranted. If we were to instead apply updated cost share weights for purposes of the PE GPCI and PFS ratesetting for CY 2028 or a later calendar year, we would be required under section 1848(e)(1)(C) of the Act to phase in the GPCI adjustments over 2 years. We sought comments on whether, in that case, it would be appropriate to similarly apply a transition to implement updated cost share weights for purposes of PFS ratesetting as well, and refer readers to section II.B and VII. of this final rule for more discussion regarding the alternatives considered and impacts of a phase-in of updated cost share weights in PFS ratesetting. The proposed CY 2026 GPCI cost share weights are displayed in Table AN-1. We note that the 2017-based MEI cost share weights as finalized in section II.M. of the CY 2023 PFS final rule (87 FR 69688 through 69708) are also displayed in Table AN-1 for awareness regarding potential future rulemaking and GPCI updates. As previously discussed, the PPI and CPI Survey data lack the specific breakdown of practice expense that we would need to consider its use to weight the four components of the PE GPCI for CY 2026, therefore, we refer readers to section VII. of this final rule for more discussion regarding a possible derivation of cost share weights for use in the PE GPCI from the PPI and CPI Survey for awareness regarding potential future rulemaking and GPCI updates.

TABLE AN-1: GPCI COST SHARE WEIGHTS FOR CY 2026

Expense Category	Current and CY 2026 GPCI Cost Share Weights (2006-based MEI)	2017-based MEI Cost Share Weights*
Work	50.866%	47.522%
Practice Expense	44.839%	51.129%
- Employee Compensation	16.553%	25.450%
- Office Rent	10.223%	5.683%
- Purchased Services	8.095%	13.419%
- Equipment, Supplies, Other	9.968%	6.576%
Malpractice Insurance	4.295%	1.349%
Total	**100.000%**	**100.000%**

*As finalized in the CY 2023 PFS final rule (87 FR 69688 through 69708)

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in Frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be Frontier States. In general, a Frontier State is one in which at least 50 percent of the counties are "frontier counties," which are those that have a population per square mile of less than 6. For more information on the criteria used to define a Frontier State, we refer readers to the FY 2011 Hospital Inpatient Prospective Payment System (IPPS)/Long-term Care Hospital PPS final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2026 PFS proposed rule. The qualifying states are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we will apply a 1.0 PE GPCI floor for these states in CY 2026.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the

national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-state locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously in the rest-of-state locality or locality 3 and are now in MSAs were a blend of two-thirds of the GPCI value calculated for the year under the MSA-based locality structure, and one-third of the GPCI

value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by one-sixth in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of five-sixths of the GPCI value for the year under the MSA-based locality structure, and one-sixth of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We note that while the phase-in for transition areas is no longer applicable, the hold-harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be one-half of the adjustment that otherwise would be made. For a comprehensive discussion of this

provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two former unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties – San Francisco, San Mateo, Alameda, and Contra Costa counties – across three former unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers; and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. In light of the foregoing, for CY 2023, we proposed and finalized to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we proposed and finalized to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to four, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we noted that we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange

Cnty). The refinement finalized in the CY 2024 PFS final rule (88 FR 78985 through 78987) ultimately changed the number of distinct fee schedule areas for payment purposes in California from 32 to 29. We noted that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we needed to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. We noted that these changes do not have any payment implications under the PFS.

h. Alternatives Considered Related to List of Occupation Codes used in the Work GPCI Calculation

As explained in the Work GPCIs section above, we utilize a refined list of occupation groups and codes from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) data to calculate the work GPCI. Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OEWS data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs. For the CY 2023 GPCI update, we reviewed the occupation codes and groups used to capture geographic variation in professional wages to assess other potential codes and groups that could be used in addition to the current selections to calculate the work GPCI, with significant consideration given to the extent to which the data exist in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). Based on our review and commenters' response to the proposals, we finalized the addition of two new occupation groups (and their corresponding occupation codes), Management Occupations and Business and Financial Operation Occupations, to the preexisting seven occupation groups, and four new occupation codes to the pre-existing Computer, Mathematical, Life, and Physical Science group, and three occupation codes to the pre-existing Social Science, Community and Social Service, and Legal group in the CY 2023 PFS final rule (87 FR 69621 through 69625). The practical effect of the addition of these occupation groups and codes on the work GPCI was minimal because the statute at section 1848(e)(1)(A)(iii) of the Act requires that the work GPCI reflect only one quarter of cost differences, but their inclusion added meaningful data regarding the geographic variation in professional wages for CY 2023.

In the CY 2023 PFS final rule (87 FR 69631), some commenters stated that our methodologic changes to the work GPCI occupation groups and codes create unnecessary complexity and limited transparency. The commenters stated that CMS did not provide an impact analysis or criteria for

inclusion (that is, how well it correlated as a proxy) other than significant consideration to the extent to which the data exists in the file (data existence) and how well the occupation codes are represented in the data (data sufficiency). The commenters stated that, without further explanation, two additional occupation groups were added to the previous seven occupation groups, which increased the greater than 100 current occupation codes by 60. A commenter believed that it is unlikely that the cumulation of so many professions will accurately reflect the relative difference in work of a single profession such as a physician; the commenter stated that, if one were to compare the BLS OEWS data file used for the work GPCI with that of the healthcare provider dataset, there is a discordance. The commenters agreed that the healthcare provider dataset should not be used for developing the work GPCI due to circularity, but believe it could be used to validate the proposed work GPCIs and to identify a much smaller subset of professions that would act as more reliable proxies than what was proposed. The commenters urged CMS to apply a smaller number of professions to the work GPCI, as they thought that doing so would result in a more reliable and accurate proxy for physician work, and provide more information about the correlation between physician work and the proxy professions to allow the public to verify its accuracy.

In response to commenters, we noted that we do not claim the proxy professions themselves, or the absolute wages of the proxy professionals are correlated to physician wages, but rather, that the geographic variation in proxy professional wages is similar to the geographic variation in physician wages.

We believed that there would be similar geographic variation if one were to compare the BLS OEWS data used for the work GPCI with data from a healthcare provider dataset. We continue to believe in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals across an array of industries vary. Further, we welcomed opportunities to discuss data sources that can be used to validate the work GPCI, similar to the analysis that we performed for residential and commercial rent data used for the office rent index for CY 2023.

For CY 2026, we analyzed the potential effect of using a consolidated set of occupation codes on the work GPCI and compared that effect to changes in work GPCI values that would occur utilizing the standard set of occupation codes, as finalized for CY 2023. We acknowledge that the use of a more parsimonious set of occupations could be an improvement if it results in essentially the same work GPCI

values with increased simplicity and clarity for interested parties. We explored approaches to condense the list of occupation codes used in a more systematic manner, with the establishment of inclusion criteria for an occupation code such as level of education attainment and data completeness. For our analysis, we identified 274, 157 and 90 occupation codes with at least 50 percent, 75 percent, and 90 percent having a Bachelor's Degree or higher, excluding occupation codes in Group 29 that are paid on the Fee Schedule, respectively from the May 2023 OEWS data. We then applied various data completeness criteria thresholds to these occupation codes with wage data for at least 50 percent, 75 percent, and 90 percent of U.S. counties, resulting in the number of occupation codes displayed in Table AN-2.

TABLE AN-2: DATA EXISTENCE FOR CODES THAT MEET VARIOUS EDUCATION ATTAINMENT THRESHOLDS: AT LEAST 50 PERCENT, 75 PERCENT OR 90 PERCENT WITH A BACHELOR'S DEGREE OR HIGHER, EXCLUDING GROUP 29 OCCUPATION CODES THAT ARE PAID ON THE FEE SCHEDULE

	Bachelor's Degree or higher ≥ 50%		**Bachelor's Degree or higher ≥ 75%**		**Bachelor's Degree or higher ≥ 90%**	
	274		157		90	
Number of Codes	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Codes with wage data for at least 50% of U.S. counties	112	41%	57	36%	23	26%
Codes with wage data for at least 75% of U.S. counties	69	25%	31	20%	8	9%
Codes with wage data for at least 90% of U.S. counties	45	16%	19	12%	4	4%

* Note: Prosthodontists (1) 29-1024 is not in the MSA-level data file that is used for analyzing data completeness. Wage data is only available at the national level in file "all_data_M_2023.xlsx". Therefore, the starting number of codes is 273, 156, and 89.

Of these scenarios with various thresholds of the education attainment and data completeness inclusion criterion, we investigated two scenarios compared to the standard CY 2026 GPCI: (1) occupation codes with at least 75 percent of Bachelor's Degree or Higher excluding Group 29 and wage data for at least 50 percent of U.S. counties, resulting in a list of 57 occupation codes; and (2) occupation codes with at least 75 percent of Bachelor's Degree or Higher excluding Group 29 and wage data for at least 75 percent of U.S. counties, resulting in a list of 31 occupation codes from the May 2023 OWES data. Under these two scenarios, the work GPCIs result in changes relative to current CY 2025 work GPCI values that are nearly identical to those under the standard CY 2026 GPCI update, as shown in Table AN-3.

TABLE AN-3: DISTRIBUTION OF WORK GPCI CHANGE UNDER CONSOLIDATED OCCUPATION CODE LISTS, TRANSITION VALUES FOR CY 2026 COMPARED TO CY 2025 VALUES

SIZE OF CHANGE IN MEASURE	Standard CY 2026 GPCI Update	BACH 75 DATA 50	BACH 75 DATA 75
	Number of Payment Areas	Number of Payment Areas	Number of Payment Areas
< -10%	0	0	0
-10% to < - 4%	0	0	0
-4% to < -1.5%	13	12	13
-1.5% to < -0.5%	36	37	37
-0.5% to < 0.5%	53	54	53
0.5% to < 1.5%	7	6	6
1.5% to < 4%	0	0	0
4% to < 10%	0	0	0
10% or more	0	0	0

Standard CY 2026 GPCI Update: reflects changes to occupation codes as described in Interim Report, using the same approach as in previous updates
BACH 75 DATA 50: includes occupation codes with ≥75% Bachelors' degrees (or higher) and data available for ≥50% of U.S. counties
BACH 75 DATA 75: includes occupation codes with ≥75% Bachelors' degrees (or higher) and data available for ≥75% of U.S. counties

Based on the two scenarios' changes relative to current CY 2025 work GPCI values that are nearly identical to those under the standard CY 2026 GPCI update, we sought comment on the potential to establish clear inclusion criteria for occupation codes for the calculation of the work GPCI in future GPCI updates. We note that a smaller, standardized list of occupation codes that meet rigorous and clearly established thresholds for education attainment and data completeness would aid transparency in the work GPCI and be responsive to the commenters' requests.

Similar to the finalized addition of occupation groups and codes for the CY 2023 GPCI update, the practical effect of limiting the occupation groups and codes on the work GPCI would be minimal because the statute at section 1848(e)(1)(A)(iii) of the Act requires that the work GPCI reflect only one quarter of cost differences, but the limitation could aid transparency and allow for a greater degree of precision when tracking changes in geographic variation in professional wages across GPCI update years.

i. GPCI Update Summary

As explained in the Background section above, section 1848(e)(1)(C) of the Act mandates the periodic review and adjustment of GPCIs. For each periodic review and adjustment, we published the proposed GPCIs in the PFS proposed rule to provide an opportunity for public notice and comment and allow us to consider whether any revisions in response to comments are warranted prior to implementation. The proposed CY 2026 updated GPCIs that we proposed for the first and second year of

the 2-year phase-in, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our website under the supporting documents section of the CY 2026 PFS final rule web page at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.

We noted that in recent GPCI updates, commenters have stated that there is a lack of transparency into the GPCI data and methodology used to derive the GPCIs. In response to the CY 2023 PFS proposed rule, a commenter stated that they cannot accurately validate CMS' GPCI calculations because there is little transparency and access to the data and methods used. The commenter stated that they submitted a comment on the CY 2022 PFS proposed rule urging CMS to provide more transparency into the GPCI calculations in general, including a more detailed description of the step-by-step methodology and the specific data files used to derive the GPCIs. In addition to making the RVUs by county available, the commenters also suggested CMS to make available the source data for the work GPCI by county, the source data for each component of the practice expense GPCI, and all budget neutrality adjustments and calculations.

The commenters stated that CMS provided these data prior to 2020 and that they used it to reproduce and validate the CMS methodology for calculating the GPCIs each year.
In the CY 2023 PFS final rule, in response to these comments, we referred readers to the step-by-step instructions provided in the final report, "Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS," on our website located under the supporting documents section for the CY 2023 PFS final rule at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices. We also referred readers to Table 4.A.1: Summary of Elements Required for GPCI Calculation in the final report, and the previous discussion, for the data sources used for the work GPCI and each component of the practice expense GPCI. As noted in the proposed and final rules for each GPCI update, we discuss the years and timeframes of data used from each source. We note that we provide web links to the publicly-available data sources used in the GPCI updates, the methodological parameters, as well as an overview of how we develop each GPCI component in the interim and final reports published with each proposed and final rule containing a GPCI update. This practice is consistent with previous updates. We also note that the budget neutrality adjustment and statutory floors applied after the budget neutrality adjustment are detailed in the note, "CY 2023 GPCI Update Note_County_Data," on our website located

under the downloads section for the CY 2023 PFS proposed and final rules at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices. We also reminded commenters that, in response to the commenters' concerns expressed in rulemaking for the CY 2020 GPCI update, we included more detailed steps in the final report, "Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Phys Fee Sched_v19Feb2020", which is available on the CMS website under the downloads section of the CY 2020 PFS final rule to assist interested parties in navigating these data. Additionally, as part of our ongoing commitment to transparency, we post the county-level data that we use to develop the proposed GPCIs, which allows interested parties to further examine and replicate our GPCI methodology. This file is also available on the CMS website under the Downloads section for the PFS, titled "CY 2023 Proposed Rule GPCI County-Level Data File." We believe that we sufficiently addressed previous commenters' concerns for the CY 2023 GPCI update in the proposed and final rules and aforementioned CY 2020 and CY 2023 interim and final reports, but we sought comments related to any additional information specific to what data was provided prior to 2020 that is no longer provided. Based on a comparison of data and information in the interim and final reports, as well as the data file downloads, we have not identified any information or data that we have discontinued since 2020, as commenters have claimed. We sought feedback related to specific information and data that would aid transparency in a GPCI update.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns over the expiring 1.0 GPCI work floor. Some of the commenters stated that if the 1.0 GPCI work floor is not extended, this would result in negative impacts, especially in rural and underserved areas. A commenter also stated that CMS should apply any claim adjustment automatically should there be a delay in enactment of an extension of the GPCI work floor policy, with a retroactive implementation date.

Response: The 1.0 work GPCI floor is established by statute and expired on September 30, 2025 (**NOTE: If necessary, this date may be changed after the next round of clearance**). CMS does not have the authority to extend the 1.0 work floor beyond the September 30, 2025 expiration and will process claims in accordance with statutory and regulatory requirements.

Comment: Several commenters opposed CMS' proposed CY 2026 GPCI decreases for Arkansas. Several of these commenters requested that CMS maintain the work floor of 1.0 and freeze Arkansas' 2025 GPCI values while a comprehensive review is conducted, or recalculate the Arkansas PE GPCI using current, disaggregated data that reflects real regional cost variation within the state, or at a minimum appropriately weighs the rate based on the population centers experiencing the highest costs, which service the majority of the state's population. The commenters also stated that the current GPCI methodology ignores regional variations within Arkansas, particularly in metropolitan areas like Washington, Benton, and Pulaski Counties. A commenter requested that we establish a timeline for evaluating Medicare localities to align with Core Based Statistical Areas (CBSA) designations, to automate county-level locality splits (that is, split any country >10 percent above statewide PE input cost for 2 consecutive years), and to meet with interested parties to collaborate on solutions. The commenter also requested that we update data annually to shorten the lag for fast-growing regions, and to apply the frontier-state PE floor to HRSA-designated Health Provider Shortage Areas (HPSAs). The commenter requested that we recognize geographic variation in the supplies and equipment component of the PE GPCI and use commercial medical office rent surveys (that is, CoStar, CBRE) instead of ACS rent data.

Some of the commenters referenced the Arkansas House Concurrent Resolution 1007 (HCR1007) and stated that the Arkansas General Assembly adopted HCR1007 during the 2025 Regular Session and urged CMS to reevaluate Arkansas' GPCI treatment and create distinct PFS localities for Little Rock-North Little Rock-Conway (CBSA 30780) and Fayetteville-Springdale-Rogers (CBSA 2220). Some of the commenters also stated that the undervaluation of Arkansas' GPCI makes it challenging to recruit and retain physicians, particularly in rural and underserved areas. While a commenter recommended that CMS recognize Central Arkansas as a distinct locality to better align payment with actual costs, another commenter opposed regional Arkansas evaluation, arguing it would strain rural providers and exacerbate workforce challenges.

Response: We appreciate the commenters' feedback. However, we reiterate that the GPCIs are based on nationally-representative and publicly-available wage data from the BLS OEWS for the work GPCI and employee wage and purchased services components of the PE GPCI, and the Census Bureau's ACS data for the rent index component of the PE GPCI. We reiterate that the GPCIs are not an absolute

measure of practices costs. Rather, they are a measure of relative resource cost differences among localities compared to the national average as informed by the data and are not intended to represent or measure changes in GDP or migration. We also remind the commenters that section 1848(e)(1)(I) of the Act defines Frontier State and sets the permanent PE GPCI floor of 1.0, therefore CMS does not have the authority to apply the 1.0 Frontier State PE GPCI floor to HPSAs. Additionally, section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years, therefore CMS does not have the authority to freeze the CY 2025 GPCIs. We note that the CY 2026 GPCI update was calculated using current, disaggregated data that reflects regional cost variation within each state, as requested by the commenter, and therefore the published CY 2026 PE GPCI in Addendum E does account for county-level differences weighted by Medicare PFS RVUs and population by country (as described in the "Interim Report for the CY 2026 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule," available on the CMS website under the downloads section of the CY 2026 PFS proposed rule at https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices).

We appreciate the suggestions for revisions to the PFS locality structure. We did not propose any changes to the PFS locality structure and therefore will not finalize any changes to the PFS locality structure for CY 2026. However, we may consider changes to the PFS locality structure through future rulemaking.

Additionally, we would like to reiterate that the current PFS locality structure was developed and implemented in 1997 with minor modifications over the years. We have also considered more comprehensive changes to locality configurations. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (www.cms.gov/physicianfeesched/downloads/ReviewOfAltGPCIs.pdf) and we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757) for a detailed discussion of the public comments on the contractor's 2008 draft report detailing different locality configurations. All four of the potential alternative payment locality configurations reviewed in the report would increase the number of localities and separate higher cost, typically urban areas from lower cost, typically rural "Rest of State" areas. In general, payments to urban areas would increase while

rural areas would see a decrease in payment under each of the options studied because they would no longer be grouped with higher cost "urbanized" areas. Disaggregation of a statewide payment locality into multiple localities would generally result in urban physicians experiencing an increase in payment and rural physicians experiencing a decrease in payment. For this reason, we have stated that we would consider a petition from a state medical association that could demonstrate that it had the overwhelming support of physicians in both winning and losings areas. We did not set absolute numerical levels of support because of the uniqueness of the locality structure in each state; we said that setting a numerical level of support would limit the discretion required to properly evaluate each request. We have employed a consistent process in evaluating each request. As stated in the CY 1995 PFS rule (59 FR 63416), upon receiving a preliminary contact from a State medical society, we inform the society that at a minimum we require: (1) A formal request for the change from the State medical society, along with a copy of a recently adopted resolution requesting the change; (2) the number of licensed actively practicing physicians in the State and the number that are society members; (3) the number of society members in each local (county) society; and (4) letters from the local societies representing physicians in the losing areas indicating the level of support for the change. After evaluating this material, if we believe that the material demonstrates overwhelming support among both winning and losing physicians, we announce the proposed change in the **Federal Register**. If the public comments received demonstrate this overwhelming support, we announce the change in a final rule in the **Federal Register**. We reiterated in the CY 2010 PFS final rule (74 FR 61758), that in the event we decide to make a specific proposal for changing the locality configuration, we would also provide extensive opportunities for public input (for example, Town Hall meetings or Open Door Forums, as well as opportunities for public comments afforded by the rulemaking process).

Regarding alternative data sources for office rent data, we note that our efforts are ongoing to identify a publicly available, robust, nationally representative commercial rent data source that could be made available to CMS for this purpose. We refer readers to the CY 2023 PFS final rule (87 FR 69625 through 69630) where we undertook a comprehensive analysis of alternatives to the ACS data and concluded that there is still no acceptable national data source available for physician office or other comparable commercial rents, and therefore, we proposed to continue to use county-level residential rent

data from the ACS as a proxy for the relative cost differences in commercial office rents for the proposed CY 2023 update, and have done so in calculating the CY 2026 GPCIs as well.

With regard to the supplies, equipment, and miscellaneous expense cost index component of the PE GPCIs, we note that we made no proposals regarding our current policy for this component of the PE GPCI. We have stated that we believe there is a national market for these items and there is not significant geographic variation in those costs, and as such we assign a value of 1.00 for this component for each locality, consistent with the national average. The commenter did not provide any data or information to quantify the variation of costs of supplies, the amount of supplies lost to expiration dates, or national suppliers' order minimums in contrast to a rural specialty practice's demand for these supplies. We encourage the commenter and other interested parties to submit data supporting their assertions for consideration in future rulemaking; specifically, we would be interested in information regarding potential data sources for shipping costs and the costs of medical equipment and supplies for different geographic regions. Ideally, the potential data sources are accessible to the public, available on a national basis for both urban and rural areas and updated regularly. Similarly, we have previously attempted to locate data sources specific to geographic variation in shipping costs, and we found no comprehensive national data source for this information, and therefore, we have not been able to quantify variation in costs specific to islands or rural communities.

Comment: A few commenters provided feedback on the proposed CY 2026 GPCIs for California. One of the commenters expressed support for the smooth transition to the new physician geographic payment localities in California and supported the proposed GPCIs for 2026 based on accurate data analysis. Another commenter stated concerns that the GPCI fails to capture the true variation in physician compensation and practices in high-cost regions, like Northern California. The commenter also stated that by statute, the work GPCI only accounts for 25 percent of local cost differences compared to the national average, systemically understating costs in high-cost areas.

Response: We appreciate the commenters' feedback and support of our proposals and locality transitions over the last decade. We would also like to reiterate that the GPCIs are based on nationally representative and publicly available wage data from the BLS OEWS for the work GPCI and employee wage and purchased services component of the PE GPCI, and the Census Bureau's ACS data for the rent

index component of the PE GPCI. The GPCIs are a measure of the relative resource of cost differences among localities compared to the national average as informed by data (not a measure of absolute costs).

Comment: A commenter stated that the GPCIs for Hawaii do not account for the unique costs of providing medical services in Hawaii, a non-contiguous state. The commenter stated that the work GPCI is flawed for Hawaii due to the State's high cost of living, significant health workforce shortages and issues with the proxy professional wages used by CMS to calculate payments. The commenter also stated that in 2008, section 134 of Pub. L. 110-275 implemented a 1.5 GPCI work GPCI floor for all counties in the Alaska locality. However, despite facing similar challenges as a non-contiguous state, Hawaii did not receive a similar GPCI adjustment. The commenter recommends that CMS institute a 1.5 work GPCI floor for the Hawaii PFS locality to address these issues and ensure parity for non-contiguous states. The commenter stated that this adjustment would help reflect the true cost of physician services in Hawaii and support the recruitment and retention of healthcare professionals in the state.

Response: We reiterate that the GPCIs are based on nationally represented and publicly-available wage data from the BLS OEWS for the work GPCI. The GPCIs are a measure of relative resource cost differences among localities compared to the national average as informed by the data (not a measure of absolute costs). We remind commenters that the work GPCI value for Alaska is not based on the data for that State, instead section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for Alaska. Similarly, section 1848(e)(1)(I) of the Act sets a permanent PE GPCI floor of 1.0 for the Frontier States. These statutory requirements are State-specific, and therefore we do not have the authority to extend a work GPCI floor to Hawaii.

Comment: A commenter expressed concern about the proposed CY 2026 GPCI decreases for some localities in Texas. The commenter requested that we recalculate the GPCIs for Texas using accurate, localized economic data that reflects the State's economy and inflationary pressures. They also requested that we revise the GPCI methodology to reflect real-world, region-specific economic conditions.

Response: Because Medicare is a national program, and section 1848(e)(1)(A) of the Act requires us to establish GPCIs to measure relative cost differences among localities compared to the national average, we believe it is important to use the best data sources that are available on a nationwide basis.

These data sources should be regularly updated and retain consistency area-to-area, year-to-year. We welcome opportunities to discuss alternative data sources with interested parties and to incorporate such data, as appropriate in the GPCI calculation process, through our standard annual rulemaking process.

Comment: A commenter raised concerns about the GPCI for Rhode Island. The commenter stated that Medicare reimburses Rhode Island at the lowest rate compared to Connecticut and both regions of Massachusetts. This has led to the healthcare workforce leaving Rhode Island and increasing financial burdens to practices in Rhode Island. The commenter suggested that CMS review the GPCI for Rhode Island to prevent further loss of professionals, diminishing access to care, and impacts on healthcare costs.

Response: We reviewed the Rhode Island GPCI value and believe it is appropriate based upon the data sources and methodology used to calculate the GPCIs. We would like to reiterate that the GPCIs are based on nationally representative and publicly available wage data from the BLS OEWS for the work GPCI and employee wage and purchased services components of the PE GPCI, and the Census Bureau's ACS data for the rent index component of the PE GPCI. The GPCIs are a measure of relative resource cost differences among localities compared to the national average as informed by the data (not a measure of absolute costs). We welcome opportunities to discuss alternative data sources with interested parties and to incorporate such data, as appropriate in the GPCI calculation process, through our standard annual rulemaking process.

Comment: A commenter stated that the "rural vs non-rural distinctions" in the GPCI locality structure are outdated, especially in the post-pandemic employment landscape. The commenter noted two significant shifts: the predominance of remote work in healthcare and the widespread nature of travel work in clinical areas. Additionally, the commenter stated that Mississippi is the most medically underserved state, with most counties designated as a HPSA. The commenter requested that the current GPCI locality structure be reevaluated and replaced.

Response: We appreciate the commenter's feedback regarding the evolving healthcare landscape and may consider changes to the PFS locality structure through future rulemaking. We welcome any additional feedback from interested parties regarding the changing landscape of healthcare, specifically regarding how to appropriately account for remote work and travel work in the PFS locality structure and GPCI methodology, through our standard annual rulemaking process.

Additionally, section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three GPCI components, and section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCI at least every 3 years. Based on new data, GPCI values may increase or decrease.

Comment: A commenter expressed concerns regarding the disparities in the GPCI that affect healthcare providers in rural and underserved areas. The commenter stated that Iowa ranks 47th out of 50 states for total GPCI, leading to inequitable payment for providers in the region. The commenter recommended that CMS either remove the GPCI altogether or implement a national GPCI floor to ensure minimum equitable payment. The commenter states that this change is essential to support recruitment, retention, and access to care in rural states like Iowa, as the current methodology does not accurately reflect the costs of operating clinical practices in low-GPCI areas and undermines health equity goals.

Response: Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. They are a measure of relative resource cost differences among localities compared to the national average as informed by the data. Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which was extended by many successive amendments to the statute through September 30, 2025. Given these statutory requirements, CMS does not have the authority to remove the GPCI altogether or implement a national GPCI floor.

Comment: Several commenters provided feedback on the 2017-based MEI cost share weights and the weights based on Physician Practice Information[123] (PPI) and Clinician Practice Information[124] (CPI) Survey data for purposes of alternatives considered for the CY 2026 PE GPCIs and PFS ratesetting and for future rulemaking.

A couple of commenters suggested using the PPI and CPI data to update the MEI cost share weights. They expressed concerns regarding using outdated 2006-based MEI cost share weights and recommend using more recent data. One of the commenters requested that CMS reconsider using the 2006 MEI cost share weights and incorporate the AMA's Physician Practice Information Survey (PPIS) data into the CY 2026 update. The commenter requested CMS to provide a clear timeline and plan for

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[123] https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.
[124] https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.

addressing gaps identified in the PPI and CPI Survey dataset. The other commenter stated for the CY 2026 MEI and GPCI weights, CMS should use PPI and CPI Survey data to implement updated shares of work, practice expense, and professional liability insurance (PLI), which results in the following distribution: work = 54.4 percent; PE = 43.8 percent; and PLI = 1.7 percent. The commenter recommended that the updated CY 2026 GPCIs be phased in over 2 years. Additionally, the commenter recommended that CMS modify its proposed mapping of the PPI and CPI survey data categories for use in updating the PE GPCI.

A couple of commenters support maintaining the current 2006 MEI cost share weights to update the CY 2026 GPCI. One of these commenters reviewed the alternative derived weights from the most recent PPI and CPI survey data for the GPCIs and found them problematic and agreed with CMS' reasons for maintaining the current 2006 MEI cost share weights. The commenter was troubled by the significant difference between the current and 2017-based cost share weights and found that the 50 percent mapping of administrative, overhead and other categories of the PPI and CPI survey to the purchased services and office rent component of the PE GPCI to be arbitrary. The commenter continued to state that the revised cost weights are not supported by other data and cited a recent Medical Group Management Association (MGMA) survey of group practices which estimated provider income (that is, physician work) to account for 30 to 40 percent of revenue, labor (support staff) was the largest component of practice expenses, accounting for 25 to 30 percent of revenue, rent accounting for 5 to 10 percent of costs (6 percent of revenue) and malpractice accounting for 3 to 5 percent of costs. The commenter stated they would not expect CMS to use MGMA data to develop weights but believe proposed weights should align with such findings. Therefore, the 2017-based MEI cost share weights and the weights based on PPI and CPI survey data more closely align with the MGMA data and their understanding of practice costs in California. However, the commenter stated that rather than supporting one of the two proposed MEI alternatives, they recommended that CMS convene a new technical advisory panel to make recommendations for reconciling the differences in work and practice expenses between physician and non-physician owned practices, safeguarding accurate payment to the physician owned practices without overpaying non-physician owned practices. The commenter stated that the technical advisory panel should make recommendations on the practice expense weights and, if there are significant differences in the

purchased service component cost shares, the panel should review and make recommendations regarding the labor-related share. In addition, the commenter recommended that updates to the cost share weights occur simultaneously with updates to the GPCIs to provide greater consistency and stability between updates and maintaining the 2-year phase in.

A couple of commenters recommended using the 2017-based MEI cost share weights. A commenter recommended that CMS implement the 2017-based MEI cost share weight with a multi-year transition period to help physician practices and other Part B providers adjust to any redistributive effects. Another commenter expressed concerns with using the 2006-based MEI cost share weights, stating that relying on nearly 20 years old data would significantly mispresent current practice costs. The commenter stated that continuing to base payments on outdated inputs risked widening the gap between actual costs and Medicare payments, threatening the financial sustainability of providers and ultimately access to care. The commenter recommended for CMS to use more recent data sources, such as the 2017-based MEI cost share.

Response: We appreciate the commenters for their support of our proposal and may consider the feedback for possible future rulemaking. We remind commenters that, for the CY 2026 GPCI update, we had concerns about the potential redistributive effects that implementing the 2017-based MEI would have on PFS payments. Additionally, we received data from the AMA's PPI and CPI Surveys. However, these data lack the specific breakdown of practice expense that we needed to consider its use to weight the four components of the PE GPCI for CY 2026. We also note that maintaining the 2006-based MEI cost share weights for the CY 2026 GPCI update preserves consistency in the data used to update both the GPCI and PFS ratesetting inputs for CY 2026.

Comment: Several commenters commended CMS for exploring alternatives to simplify the work GPCI development by reducing the number of occupations used. A commenter stated that of the two scenarios investigated, they favor the 75 percent bachelor's degree or higher and the greater than 75 percent county wage data availability due to its greater simplicity and similar accuracy, which are the criteria we use to assess alternatives. The commenter questioned why the greater than 90 percent criteria were not reported regarding accuracy relative to the current GPCIs, as these criteria would further simplify the methodology by reducing the number of occupation codes included in the calculations. The

commenter stated that if these more stringent criteria had similar accuracy in measuring relative cost differences, the commenter would favor them. Additionally, the commenter requested the specific derived BLS OEWS national level files and cross industry MSA level wage files for the work GPCI, and the wage and purchased services PE GPCI as described in the Interim Report's methodology of Work and PE GPCI formation be made publicly available. The commenter also requested additional information as to whether the purchased services indices included a non-labor related adjustment and, if so, what that adjustment was. The commenter appreciated CMS' willingness to provide additional data to verify the GPCI methodology.

Response: We appreciate the commenters for their support of our efforts and may consider the feedback for possible future rulemaking. We appreciate the commenter's requests for additional information and data files and welcome the opportunity to discuss these requests in more detail with the interested party. We note that we may consider modifications to the list of occupation codes used in the calculation of the work GPCI, which would simplify the calculation and provide opportunity to improve clarity of our documentation.

Comment: A few commenters supported the proposed updates to the GPCIs.

Response: We appreciate the commenters for the support of our proposed CY 2026 GPCI updates.

After consideration of public comments, we are finalizing the CY 2026 GPCI updates as proposed. The final GPCIs and summarized GAFs are displayed in Addenda D and E to this final rule.

III. Other Provisions

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021) (hereinafter referred to as "the Infrastructure Act") amended section 1847A of the Act to add a provision requiring manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as "refundable drug") for calendar quarters beginning January 1, 2023.

The calculation of the refund is codified at § 414.940(c). For a new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

- The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;
- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69731), we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics. In the CY 2024 PFS final rule (88 FR 79047 through 79064), we finalized an increased applicable percentage for two categories of drugs with unique circumstances, codified at § 414.940(d). These categories include: certain drugs with a low-volume dose (that is, where the volume removed from the vial or container containing the labeled dose does not exceed 0.1 mL or

falls between 0.11 mL and 0.4 mL); and orphan drugs furnished to fewer than 100 unique beneficiaries. Drugs with an increased applicable percentage are listed on the CMS website.[125]

b. Application for Increased Applicable Percentage

Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary to increase the applicable percentage for a refundable drug that has unique circumstances through notice and comment rulemaking. In the CY 2024 PFS final rule (88 FR 79057 through 79060), we finalized an application process (CMS-10835, OMB 0938-1435) by which manufacturers could apply for an increased applicable percentage for a drug and may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We explained that manufacturers could benefit from a formal process through which they can provide information, including that which may not be publicly available, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of its unique circumstances.[126,127] We finalized the application deadline of February 1 of each year, adopted a deadline of August 1 for the FDA-approval of the drug and the deadline for notifying and submitting the FDA-approved label to CMS of September 1 of the year before the year in which the increased applicable percentages would apply. We codified this process at § 414.940(e). The application process requires the applicant to provide a written request comprising FDA-approved labeling for the drug; justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage. Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage beginning as of the following January 1. The collection of information requests associated with the application process (CMS-10835, OMB 0938-1435) would remain unchanged under this final rule.

As we discussed in the CY 2026 PFS proposed rule (90 FR 32538 through 32540), we received two applications for increased applicable percentage for consideration. Both applicants submitted the

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[125] https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs
[126] https://www.cms.gov/files/document/drugs-increased-applicable-percentage.pdf
[127] https://www.cms.gov/files/document/orphan-drugs-increased-applicable-percentage-calendar-quarters-2023.pdf

information required at § 414.940(e)(1), including, as applicable, the FDA-approved labeling for the drug, justification for consideration for increased applicable percentage, and justification for the requested applicable percentage.

The first application for increased applicable percentage for CY 2026 was from the manufacturer of Leukine® (sargramostim),[128] who has resubmitted a request for a 72 percent applicable percentage after applying in the previous year. Leukine® is a leukocyte growth factor with five FDA-approved indications in hematological malignancies and one indication for post-radiation exposure to increase white blood cell counts. The applicant's submitted FDA-approved labeling for the drug did not include the adjuvant uses described in the application (further described later in this paragraph) due to ongoing cancer vaccine adjuvant trials. The applicant reemphasized that multiple sponsors are in late-stage development, with a total of 22 Phase II and Phase III clinical trials, an increase from 16 reported in the previous year, investigating Leukine® as a vaccine adjuvant for oncology indications, specifically to stimulate the immune response of dendritic cells when used alongside these vaccines. We noted that cancer treatment vaccines differ from the vaccines that protect against viruses, such as the influenza virus. Instead of preventing disease, cancer treatment vaccines aim to stimulate the immune system to attack existing cancer cells in the body.[129] The applicant stated that it has no ownership stake in the development of these cancer treatment vaccines and does not possess control or influence over the design and execution of the clinical trials. They further explained that the estimated completion dates for Phase III clinical trials vary, with the earliest expected in late 2025[130] and the latest in March 2029.[131] The adjuvant use of Leukine® in predetermined dosage is distinct from its six FDA-approved indications, all of which have dosages that are based on body weight or body surface area (BSA). The adjuvant use dosages of Leukine® in clinical trials are generally much smaller than dosages for indications in the FDA-approved labeling. The smallest dose of Leukine® used for vaccine adjuvant purposes of which the applicant is aware (that is, 70 mcg) would lead to as much as 72 percent of the drug being discarded from a single-dose 250 mcg lyophilized vial, which is the only size available commercially. The applicant suggests that

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[128] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103362s5249lbl.pdf.
[129] https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html.
[130] https://clinicaltrials.gov/study/NCT04229979.
[131] https://clinicaltrials.gov/study/NCT05100641.

if use of these small doses were to become more common for an approved indication, the percentage of discarded units could increase the discarded drug refund amount that could be owed by the applicant, even though the applicant lacks control or knowledge of the potential variability of the discarded amounts that may occur if Leukine® were used for such purposes. The applicant notes that if another manufacturer were to seek FDA approval for adjuvant use of sargramostim but was not involved in its production, the available single-dose 250-mcg vial presentation of Leukine® would likely not be optimized for the small doses being studied in these trials.

In the CY 2026 PFS proposed rule (90 FR 32539), we explained that as part of CMS' review of the application, we analyzed existing claims data from the first quarter of 2018 through the last quarter of 2024 and found the percentage of units discarded for the HCPCS code for Leukine® (J2820) ranged from 1.2 percent to 3.8 percent, which is below the applicable percentage of 10 percent. In addition to the low overall discard rate, the percentage of units discarded showed a standard deviation of less than 1 percent across quarters. This is notably lower than the 6.21 percent average standard deviation observed for rarely utilized orphan drugs, as reported in the CY 2024 PFS final rule (88 FR 52393). The low standard deviation indicates minimal quarter-to-quarter variation, with the percentage of units discarded tightly clustered around a 2.2 percent mean. For context, approximately two-thirds of the quarterly percentage values for units discarded fall within 1 percentage point above or below the mean, highlighting the consistency and stability of the trend over the 7-year period. Therefore, although the applicant suggests otherwise, this data did not follow a statistical distribution similar to that considered for rarely-utilized orphan drugs meeting the criteria at § 414.940(d)(5), which may not have a normal statistical distribution from quarter to quarter, potentially resulting in highly variable refund amounts as compared with the variability of drugs administered to a higher number of beneficiaries. Since we did not yet know the impact of a new adjuvant indication with a type of immunotherapy commonly referred to as cancer vaccines[132] on the current percentage of units discarded, we did not propose an increased applicable percentage in the CY 2025 PFS proposed rule. Additionally, because it was not yet known whether sargramostim would be approved for additional indications and dosages, as indicated in the information provided by the applicant, and the available data did not provide enough information for CMS to

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[132] https://www.cancerresearch.org/treatment-types/cancer-vaccines.

determine whether Leukine® had unique circumstances that would prompt an increase in the applicable percentage, we did not propose an increase in the applicable percentage for the drug in the CY 2025 PFS proposed rule. The applicant agreed with CMS' rationale for this decision.

As we stated in the CY 2026 PFS proposed rule (90 FR 32539), because we are maintaining our determination from the CY 2025 PFS proposed rule, we did not propose an increase in the applicable percentage for Leukine® at this time. The applicant may reapply in a future application cycle when more information, such as FDA-approved labeling reflecting new indications or dosages, becomes available.

In the CY 2026 PFS proposed rule (90 FR 32539), we also discuss that the second application was from the manufacturer of Jelmyto® (mitomycin for pyelocalyceal solution)[133] who requested an additional 10 percent increase to the 35 percent applicable percentage finalized in the CY 2023 PFS final rule (87 FR 69727 through 69731), bringing the total applicable percentage to 45 percent. We noted that Jelmyto® is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC), a rare cancer with approximately 7,000 new annual cases[134] in the United States. According to the applicant, Jelmyto® dosing ranges from 20 mg to 60 mg per single treatment, with the specific dose determined by kidney volume measurements obtained through pyelography.[9] In the CY 2023 PFS final rule, we stated that Jelmyto®, a drug reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, may leave a substantial amount adhering to the vial wall due to its viscosity, and making it non-extractable. This viscosity results from proprietary reverse-thermal technology (RTGel®), which enables the drug to transition from a chilled liquid at instillation into a gel at body temperature. We determined that a 35 percent applicable percentage was appropriate— accounting for 25 percent lost to adhesion (that is, an 80 mg package with maximum extractable dose of 60 mg results in at least 25 percent being discarded) and an additional 10 percent to align with drugs without unique circumstances for patients requiring less than the maximum dose of 60 mg. We disagreed that an applicable percentage greater than 35 percent should be applied to such hydrogel products, because we believe that 25 percent accounts for the hydrogel that adheres to the vial, and because we have allowed for an additional 10 percent of drug to be discarded before any refund would be owed. We noted that this

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[133] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211728s010lbl.pdf.
[134] https://www.urologyhealth.org/urology-a-z/u/upper-tract-urothelial-carcinoma-(utuc).

35 percent applicable percentage was codified at § 414.940(d)(2), with broad support from commenters, for drugs that are both reconstituted with a hydrogel and subject to variable dosing based on patient-specific characteristics.

The applicant contended that the current 35 percent applicable percentage does not account for drug loss due to kidney volume variations and different administration routes, both of which the applicant claimed meet the patient-specific characteristics outlined in § 414.940(d)(2). The applicant explained that since kidney volume cannot be determined until the pharmacy has prepared the drug and the patient is ready for administration of the initial treatment, and stated that patients with smaller-than-average kidney volumes may lead to a higher amount of drug being discarded. Additionally, they stated that the amount of Jelmyto® discarded may increase when providers choose antegrade (via nephrostomy tube) administration over the more common retrograde (via ureteral catheter) administration, as the greater drug delivery efficiency of the antegrade route may result in a lower dose required, leading to more of the drug being discarded. The choice of administration route must be determined on an individual basis, considering multiple factors, including but not limited to the risks and benefits of each route, previous history of failed administration attempts, tolerance to anesthesia, anatomical variations in the urinary tract, patient preference, and the patient's clinical presentation at the time of drug administration.[135,136,137] We noted that these patient-specific characteristics, combined with the requirement for hydrogel reconstitution, were considered when establishing the current 35 percent applicable percentage.

In the CY 2024 PFS final rule (88 FR 79057), we stated that we do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, BSA-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act. Consistent with that statement, we generally do not consider dose variations due to patient- or condition-specific characteristics to be unique circumstances

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[135] https://bjui-journals.onlinelibrary.wiley.com/doi/full/10.1111/bju.15925.
[136] https://www.sciencedirect.com/science/article/pii/S2405456923001232.
[137] https://www.jelmyto.com/hcp/pdf/jelmyto-antegrade-instillation-overview.pdf.

for the same reason. That is, manufacturers can optimize the availability of products for these circumstances to minimize discarded amounts. Therefore, we do not consider the drug loss due to patient-specific characteristics, such as variation in kidney volume and factors leading to antegrade administration, to be unique circumstances, and we did not propose an increase in the applicable percentage of 45 percent for the drug. Consistent with the CY 2023 PFS final rule, we proposed that the applicable percentage for Jelmyto® continue to be 35 percent (90 FR 32540).

The following is a summary of the comments we received and our responses.

Comment: A commenter provided feedback related to the applications received for an increased applicable percentage beginning in CY 2026. The manufacturer of Leukine® agreed with CMS' rationale, noting that there was insufficient information to determine whether Leukine® had unique circumstances that would warrant an increase, and indicated that they plan to reapply in a future cycle when more data are available. CMS did not receive any comments regarding the application for Jelmyto®.

Response: We appreciate the commenter's feedback and support for our assessment of the application and decision to not propose an increased applicable percentage at this time for Leukine®. As discussed previously in this section, the application, including reapplication, for an increased applicable percentage is due by February 1 of the calendar year prior preceding the year in which the increased applicable percentage would apply, as described at § 414.940(e).

Comment: A commenter supported the ongoing refinement to discarded drug refund policy, which the commenter stated will help reduce waste and spending within the Medicare program.

Response: We appreciate the commenter for their support.

Comment: Several commenters provided feedback regarding categories and products that the commenters believed should be considered for increased applicable percentages due to unique circumstances. A commenter suggested: (1) cell and gene therapies and other personalized therapies, given their distinct manufacturing and administration requirements; (2) a new category providing a minimum of an additional 18 months of increased applicable percentage for newly approved drugs that are developing new delivery methods and sizes; (3) drugs that treat multiple indications across diverse patient types and characteristics; and (4) exclusion of discarded units from medically unlikely edits (MUEs).

Response: We note that these comments are out of scope and direct commenters to § 414.940(e) for details regarding the application for increased applicable percentage and encourage interested stakeholders to utilize this process to submit requests for CY 2027 and future years.

Comment: Several commenters provided feedback related to information provided in the discarded refund reports. Some of these commenters recommended that CMS expand the data elements included in the report and standardize formats beyond the statutory minimum to improve transparency and support accurate verification. Commenters stated that the current report lacks sufficient granularity and consistency for manufacturers to independently validate refund calculations, creating compliance risks and administrative burdens. They further noted that reports have varied in format, completeness, and data elements, often requiring manufacturers to engage in dispute resolution to obtain missing information. In addition, commenters explained that publicly available Medicare datasets are inadequate due to significant time lags and requested that CMS provide claims-level data through a secure mechanism that protects beneficiary privacy. Suggested elements include the date of service, National Drug Code (NDC), HCPCS code, the ASP for the HCPCS code, allowed charges for both administered and discarded billing units with the corresponding percentage of allowed payment by CMS, and anonymized provider identifiers. Access to standardized and comprehensive data, they emphasized, would not only facilitate verification and reduce administrative burden but also enable manufacturers to identify opportunities to minimize discarded amounts of drugs through optimized packaging and vial sizes. Another commenter stated that they cannot confirm calculations, determine excess discarded amounts, or verify the accuracy of invoiced amounts in the discarded drug refund report because invoices do not specify the applicable percentage used for each drug.

A commenter recommended that CMS provide an annual, comprehensive report for all products, including those not eligible for refunds under the discarded drug refund policy or with zero refund amount, and to publish the report sooner to reduce the data lag. The commenter stated that such reporting would help manufacturers make informed decisions about post-market optimization of drug vials or packaging in alignment with the policy goals.

Response: We appreciate the commenters' input about information included in the report and the format of the report. Comments requesting expansion of data elements and a comprehensive report for all

products—including those not eligible for refunds under the discarded drug refund policy—are out of scope for this final rule. However, we may take this information into consideration for future policy development and potential operational enhancements, including formatting consistency. Regarding the applicable percentage for each drug, we maintain a publicly available website[138] that lists drugs for which an increased applicable percentage applies and updates that information periodically. Drugs not identified for an increased applicable percentage remain subject to the 10 percent applicable percentage described in section 1847A(h)(3)(B)(i)(I) of the Act. Each manufacturer has an opportunity to dispute information in the discarded drug refund report by submitting an error report as described at § 414.940(f).

In summary, after consideration of the public comments, we are finalizing no changes to the applicable percentages for Leukine® and Jelmyto®.

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[138] https://www.cms.gov/files/document/drugs-increased-applicable-percentage.pdf.

2. Average Sales Price**:** Price concessions and bona fide service fees (§ 414.804 and 414.802)

a. Background

Drugs payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as "incident to") (section 1861(s)(2) of the Act), those furnished via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and other drugs for which coverage is specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment limits for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. If CMS determines a payment limit for a drug, it is published in the Medicare Part B Drug Payment Limit File or Not Otherwise Classified (NOC) payment limit file, which are both updated quarterly.

The calculation of payment limits for such drugs payable under Part B is done on a quarterly basis using the manufacturer's ASP (as defined in § 414.902), as applicable, using methodology in section 1847A of the Act. Manufacturers are required to report ASP data to CMS under sections 1847A(f)(2) and 1927(b)(3) of the Act and are instructed to calculate the manufacturer's ASP in accordance with section 1847A(c) of the Act and § 414.804(a).

As part of that calculation of the manufacturer's ASP, required under section 1847A(c)(3) of the Act and § 414.804(a)(2), manufacturers must deduct price concessions such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program). Section 1847A(c)(3) of the Act also provides that, "[f]or years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser." The Secretary implemented an interim rule adopting those statutory categories of price concessions in 2004 (69 FR 47488). In 2006 the Secretary finalized policies for how the manufacturer's ASP is calculated, which required manufacturers to deduct all price concessions from ASP at § 414.804(a)(2).While price concessions are deducted from the manufacturer's ASP (that is, price concessions will lower the resulting manufacturer's ASP), bona fide service fees (BFSFs) are not

considered price concessions and, therefore, are not deducted when calculating the manufacturer's ASP (see § 414.804(a)(2)(ii)). In other words, BFSFs do not lower the manufacturer's ASP because they are not part of the calculation.

In the Calendar Year (CY) 2007 Physician Fee Schedule (PFS) final rule (71 FR 69665 through 69678) Medicare finalized a definition of BFSF for the purposes of calculating the manufacturer's ASP at § 414.802. The definition finalized in that final rule states that the term "BFSFs" means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. In the CY 2007 PFS final rule, we stated that the BFSF definition provides an appropriate safeguard against the potential risk for inappropriately inflated ASPs. We stated that if a manufacturer has determined that a fee paid meets the other elements of the definition of "bona fide service fee," then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity. Further, we stated (71 FR 69669) that in the absence of specific guidance in the Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices. We stated that these assumptions may be submitted along with the ASP data.

Accurate assessment and reporting of price concessions and BFSFs are essential to correctly calculating the manufacturer's ASP. Improperly classifying price concessions as BFSFs would artificially increase the manufacturer's ASP resulting in Medicare overpayments and higher coinsurance amounts paid by beneficiaries.

In December of 2022, the Office of Inspector General (OIG) published a report entitled "Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices" (hereinafter referred to as the December 2022 OIG report).[139] That report recommended CMS

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[139] Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Price, Office of Inspector General, U.S. Department of Health and Human Services. December 2022. https://oig.hhs.gov/documents/evaluation/3215/OEI-BL-21-00330-Complete%20Report.pdf.

actively review current guidance related to areas identified in the report and determine whether additional guidance would ensure more accurate and consistent ASP calculations. One area identified was how bundled sales price concessions should be incorporated into the manufacturer's ASP calculation. One manufacturer specified they would like additional guidance regarding whether unbundling a bundled arrangement should include just the discounts contingent on purchase or performance or all discounts that are part of the arrangement, how to treat bundled sales that include covered and noncovered products, and how manufacturers should identify and reallocate discounts with sales that may be considered bundled across time periods.

This report also recommended CMS give particular consideration to guidance regarding BFSFs. Manufacturers surveyed in the report expressed that there could be inconsistencies and differences in how manufacturers interpret the BFSF definition. For example, one manufacturer noted that CMS has not defined the term fair market value (FMV) for the purposes of the BFSF. The report indicated that the manufacturer would like additional guidance from CMS on the methodology that manufacturers should use to assess FMV and clarification about a timeframe after which manufacturers should reassess the FMV of BFSFs.

In addition to the recommendations from the December 2022 OIG report, we have concern that certain costs could be classified by manufacturers as BFSFs when they should instead be classified as price concessions. Further, we are concerned that certain costs that are classified as BFSFs may not represent the FMV for the service. Lastly, the current policy that manufacturers may presume none of the fees are passed on in whole or in part may allow for certain costs to be misclassified when reasonable inquiry would demonstrate that fees are indeed passed on. Such occurrences would likely impact the accuracy of ASP data that is reported to CMS each quarter.

For these reasons, we proposed policies to provide additional guidance on two aspects of the calculation of manufacturer's ASP. First, we proposed regulatory text to specify when certain fees are considered price concessions and on how manufacturers should allocate pricing for drugs sold under a bundled arrangement. Second, we proposed to revise the definition of BFSFs by (1) specifying the methodology that should be used to determine FMV and the time period after which manufacturers should reassess the FMV; and (2) further explaining what CMS considers to be sufficient evidence of

whether or not a fee is passed on in whole or in part to an affiliate[140], client, or customer of an entity. We also proposed that in the absence of specific guidance, manufacturers be required to submit any reasonable assumptions they utilize for manufacturer's ASP calculations (which is currently voluntary), including documentation of the methodology used to determine FMV and periodic reviews of FMV. We proposed that manufacturers must also submit a warranty or certification from the recipient of the fee that it is not passed on in whole or in part to an affiliate, client, or customer of an entity. Finally, we provided certain non-exhaustive examples of fees that CMS considers to be price concessions and not BFSFs.

The goal of these proposals was to avoid inaccurate calculation of the manufacturer's ASP that is used to determine Part B drug payment limits. These proposed policies would also clarify how certain costs should be considered under newer pharmaceutical business practices that may not have been considered when Medicare last finalized the definition of BFSFs in 2007.

b. Price Concessions

As discussed in the background section, the ASP statute and regulations require that the manufacturer's ASP deduct price concessions, including volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program).

Manufacturers can offer certain price concessions as part of bundled arrangements in which price concessions are treated as discounts that are tied to the purchase of the same drug or item or multiple drugs or items. They can also be discounts contingent on certain performance requirements, such as achievement of market share. In addition, price concessions as part of a bundled arrangement may include only Part B drugs or may include both Part B drugs and other products or services. These price concessions within bundled arrangements are accounted for in the calculation of the manufacturer's ASP.

We discussed bundled price concessions and considered how manufacturers could apportion such discounts to calculate the manufacturer's ASP in the CY 2007 PFS final rule (71 FR 69673 through 69676). We stated that given the potentially wide range of bundling arrangements that might exist, based on the information we had about such arrangements, we could not determine at that time whether there is

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[140] Affiliate meaning the affiliate of an entity that is receiving the fee that is providing the service.

a universal approach for treating bundled price concessions in the manufacturer's ASP calculation that would address all potential structures of bundling arrangements in a manner that would achieve our goal of ensuring the accuracy of the ASP payment methodology and preventing inappropriate financial incentives. Then, in the Medicare Payment Advisory Commission's (MedPAC) January 2007 Report to Congress, "Impact of Changes in Medicare Payments for Part B Drugs,"[141] they discussed the issue of allocation of bundled price concessions for purposes of calculating the manufacturer's ASP, noting that "some manufacturers offer provider discounts for one of their products contingent on purchases of one or more other products." In light of MedPAC's recommendation that CMS address the ASP reporting requirements for bundled products and our discussion of bundled price concessions in the CY 2007 PFS rulemaking, we stated in the CY 2008 PFS proposed rule (72 FR 38150 through 38151) that we believe specific guidance in the ASP context is warranted to ensure consistency in ASP reporting across manufacturers and to enhance the accuracy of the ASP payment system. We stated at that time that we found MedPAC's suggestion not to defer further guidance in this area compelling with respect to the potential that manufacturers may make differing assumptions in the absence of specific guidance on how to allocate bundled price concessions in the context of ASP. However, in the CY 2008 PFS final rule (72 FR 66256 through 66258), based on comments recommending a delay and to better understand the concerns stated by the commenters, we did not finalize the regulatory language changes we proposed in the CY 2008 PFS proposed rule at that time. However, we explained that in the absence of specific guidance, manufacturers may make reasonable assumptions in their calculation of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and their customary business practices.

In the 2007 Prescription Drugs final rule (72 FR 39144 through 39145), Medicaid finalized a definition of the term "bundled sale" for the purpose of calculating the average manufacturer price (AMP) and best price, which is codified at § 447.502. The definition was revised in the 2016 Covered Outpatient Drugs final rule (81 FR 5181 through 5183) and the 2020 Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid,

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[141] Impact of Changes in Medicare Payments for Part B Drugs, Medicare Payment Advisory Commission. January 2007. https://www.govinfo.gov/content/pkg/GOVPUB-Y3_M46_3-PURL-LPS78409/pdf/GOVPUB-Y3_M46_3-PURL-LPS78409.pdf.

Revising Medicaid Drug Rebate and Third Party Liability Requirements final rule (85 FR 87022 through 87024). The current definition states that a bundled sale means any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. The definition further states: (1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement; (2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle; and (3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale.

We are aware that many manufacturers currently utilize portions of the Medicaid definition of bundled sales to identify any bundled arrangements for the purposes of their ASP calculations. In addition, we noted in the CY 2008 PFS final rule (72 FR 66257 through 66258), that most commenters supported an appropriately consistent approach for the treatment of bundled price concessions with both AMP and ASP calculations. We also stated our intention at that time to remain consistent, as appropriate, with the final policy adopted in the 2007 Prescription Drugs final rule (72 FR 39144 through 39145).

As discussed in the background section, the December 2022 OIG report recommended that CMS consider providing additional guidance with regard to how bundled sales price concessions should be incorporated into the manufacturer's ASP calculation. The report stated specifically that one manufacturer requested additional guidance pertaining to bundled sales discounts for the following:

- Whether unbundling a bundled arrangement should include just the discounts contingent on purchase or performance requirements or all discounts that may be part of the underlying arrangement.
- How to treat bundled sales that include both covered products and noncovered products (that is, products for which there is no government price reporting obligation).

● How manufacturers should identify and reallocate discounts associated with sales that may be considered bundled across time periods. The manufacturer stated that CMS guidance on these types of temporal bundling will be critical because they will play an important role in the implementation and evaluation of value- and outcomes-based arrangements, which may require assessing the efficacy of a drug over multiple reporting periods.

Therefore, we proposed to add a definition of the term bundled arrangement to § 414.802, similar to that which was proposed in the CY 2008 PFS proposed rule. Specifically, we proposed the definition to state "Bundled Arrangement means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs or biologicals been purchased separately or outside the bundled arrangement." We also proposed adding paragraphs (iii) and (iv) at § 414.804(a)(2) to provide manufacturers with additional guidance on how to allocate discounts under bundled arrangements, which aligns with Medicaid's definition of bundled sale further described later in this section. This proposal aligned with our previously stated intent to remain consistent, as appropriate, with Medicaid's policy for calculating AMP and aligns with supportive comments discussed in the CY 2007 and 2008 PFS final rule discussions on this topic.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed definition of bundled arrangement, citing that aligning with Medicaid's approach is reasonable and will promote consistency in how ASP is calculated across manufacturers.

Response: We thank the commenters for their support.

Comment: Many commenters generally supported the proposed definition of bundled arrangement but were concerned with the inclusion of "purchasing patterns" and "prior purchases" in the proposed definition as examples of performance requirements, not only because of misalignment with

MDRP, but commenters stated that these words create ambiguity because they are not defined in the proposed rule nor explained why they were included. A commenter requested CMS clarify that purchasing patterns, prior purchases, or any other purchase or performance requirement applicable to the same product cannot create a bundled arrangement requiring reallocation of discounts across reporting periods.

Response: It is our objective to adopt a consistent definition of bundled arrangements that is consistent with MDRP. We are persuaded by the commenters and believe removing "purchasing patterns" and "prior purchases" from the definition of bundled arrangement is reasonable and as such, reallocation is not applicable.

Comment: A commenter requested that CMS clarify that certain phrases create objective standards based on contract text and that bundles across ASP, AMP, and BP should be verifiable and text-based.

Response: This comment is outside the scope of the final rule at this time.

Comment: A few commenters did not agree with finalizing a definition of bundled arrangement. A commenter stated that finalizing a definition of bundled arrangement would expand the universe of price concessions that would be included in ASP and therefore lower ASPs relative to where they are today. Another commenter encouraged CMS to engage in discussions before finalizing the definition to evaluate whether a universal definition of this term results in a more accurate ASP calculation. A few commenters also opposed the January 1, 2026 implementation for price concessions involved in bundled arrangements.

Response: We do not agree with the commenters' concerns regarding finalizing a definition of bundled arrangement. We believe that the adoption of a standardized definition will enhance transparency, promote consistency across interested parties, and support more accurate ASP calculations. Moreover, because many manufacturers have stated in their submitted reasonable assumptions that they currently utilize the Medicaid definition of bundled arrangements in calculating ASP, we believe the finalized policy would not be overly burdensome to implement and would better reflect current industry practice. Regarding delaying implementation, because manufacturers have used the Medicaid bundled sale definition as a reasonable assumption when calculating ASP, we are not persuaded that these new

requirements would be difficult to implement. Therefore, we are not convinced that delayed implementation of this definition is necessary.

After consideration of public comments, we are finalizing the proposed bundled arrangement definition, excluding the terms "purchasing patterns" and "prior purchases." The finalized definition is effective for sales occurring on or after January 1, 2026, which is reflected in the Medicare Part B Drug Payment Limit File beginning July 2026. We believe this aligns with our stated intent to support program alignment with MDRP and reduces administrative complexity.

Second, to address the suggestion that the agency determine whether additional guidance would be appropriate for the areas described in the December 2022 OIG report for how to account for unbundling a bundled arrangement, we note that Medicaid's definition of "bundled sale" at § 447.502 directs that discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

In other words, as noted in 81 FR 5181 through 5183, the "unbundling" of both contingent and non-contingent discounts is appropriate because "all the discounts" in the bundled arrangement should be proportionally allocated. We proposed to adopt this approach for the calculation of the manufacturer's ASP because of our stated intent for consistency with policies for AMP. Consistent application of this policy by all manufacturers reduces the opportunity for improper manipulation of the ASP calculation, providing greater certainty to CMS of the integrity of the submitted ASP. Therefore, we proposed the same regulatory language be added to § 414.804(a)(2)(iii) and (iv).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposal to allocate discounts under a bundled sale proportionally across all products.

Response: We thank the commenters for their support.

Comment: Many commenters opposed the reallocation of all non-contingent discounts in bundled arrangements, stating that the 2016 MDRP final rule does not require this. They believed that different standards between ASP and MDRP would create administrative burdens for manufacturers, contradicting

CMS' intent to align these policies. A commenter noted that reallocating non-contingent discounts would not consistently affect ASPs, while others claimed it could distort ASP values. Commenters urged CMS to allow manufacturers to make reasonable assumptions about discounts in bundled arrangements. They also requested clarification that products without financial relationships should not require reallocation of non-contingent discounts. If CMS deems reallocation necessary, commenters recommended clear regulatory language and explanations.

Response: Consistent with the 2007 Medicaid Program final rule (72 FR 39142), which was reiterated in the 2016 Medicaid Program final rule (81 FR 5181 through 5183), we consider all drugs to be within the bundled sales if: (1) Any drug must be purchased to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price; (2) there is a performance requirement (such as inclusion or tier placement on a formulary or achieving a certain level or percentage of sales for one drug to receive a discount on another drug); or (3) price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. When a manufacturer offers discounts on multiple products under a single contract (for example, to minimize the administrative burden of developing several single contracts which offer separate discounts on the multiple products) no bundled sales arrangement exists as long as all of the following conditions are met: (1) A discount or price concession is established independently for each product within the contract; (2) the purchase price under the contract is not contingent upon any other product in the contract or upon some other performance requirement (such as the achievement of market share or inclusion or tier placement on a formulary); and (3) the discount provided for any product under the contract is no greater than if the product was purchased outside of the contract.

After consideration of public comments, we are finalizing as proposed to direct that discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

Third, to address the suggestion that the agency determine whether additional guidance would be appropriate for the areas described in the December 2022 OIG report for how to allocate discounts for bundled sales, we proposed that for bundled sales containing both Medicare Part B-covered and non-

covered products, manufacturers allocate discounts proportionally as described in the previous paragraph. However, we have heard from interested parties that this method may not be sufficient to cover all cases and could potentially result in inaccurate ASPs. Bundled arrangements may vary depending upon the number and type of products included in a bundling arrangement, whether the price concessions are contingent on the purchase of only one product, the purchase of multiple products, or the inclusion of one or more products on a formulary, and the timing of the price concessions. For example, a different allocation method may be needed to account for variable costs per product in the bundled arrangement. We solicited comments on whether there are other methods of allocating discounts in these circumstances that would more accurately represent ASP.

The following is a summary of the comments we received and our responses.

Comment: MedPAC encouraged CMS to consider use of a "lower-of approach" to prevent the allocation of discounts from Part B drugs to other products. They explained that under this approach ASP could be the lower of (1) ASP with price concessions allocated across all products in the bundle; or (2) ASP with price concessions allocated only among Part B drugs in the bundle that are required to report ASP data.

Response: We may re-examine this policy consideration in future rulemaking.

Comment: A commenter affirmed that bundles across Part B-covered and non-covered products should be subject to standard bundling requirements. However, the commenter encouraged CMS to clarify that drug delivery devices that are approved under the drug approval (NDA or BLA) should be considered part of the drug, and not another product that could create a bundled arrangement, even if the delivery device is not packaged within the same National Drug Code.

Response: The suggestion that drug delivery devices approved under a drug application should be treated as part of drug to be outside the scope of this rulemaking.

After consideration of public comments, we are finalizing as proposed that for bundled sales containing both Medicare Part B-covered and non-covered products, manufacturers allocate discounts proportionally.

Finally, to address the suggestion that the agency determine whether additional guidance would be appropriate for the areas described in the December 2022 OIG report as it relates to how to reallocate

discounts associated with sales that may be considered bundled across time periods (for example, outcomes-based arrangements or value-based purchasing arrangements), we did *not* propose to adopt the portion of the Medicaid definition of bundled sale stating that value-based purchasing arrangements may qualify as a bundled sale because we are continuing to evaluate how value-based purchasing arrangements should be considered for drugs payable under Medicare Part B. We solicited comments on how discounts associated with sales that may be considered bundled across time periods could be accounted for in the manufacturer's ASP calculation.

Comment: A commenter encouraged CMS to monitor value-based purchasing arrangements going forward to help ensure this policy does not have unintended consequences. Specifically, the commenter recommended CMS consider monitoring for the prevalence of value-based purchasing arrangements via the reasonable assumptions manufacturers submit to CMS.

Response: We intend to review reasonable assumptions to monitor this policy going forward. If we have concerns with manufacturer's reasonable assumptions, we may follow up with the manufacturer. The requirement that manufacturers submit their reasonable assumptions does not change that manufacturers are responsible for submitting accurate ASP reports, and that we rely on and uses manufacturers' submission as submitted to calculate payment limits. Reasonable assumptions will be used to review industry-wise issues for potential future policy development and, in certain instances, to make referrals to law enforcement partners. Manufacturers should not expect individual feedback from us on their reasonable assumptions submissions, nor should they interpret a lack of response from us as an approval of those submissions. If we determine that a manufacturer has misrepresented information in the reporting of its ASP, CMS may refer the issue to HHS's Office of Inspector General (OIG) to determine whether a civil monetary penalty should be imposed, in accordance with section 1847A(d)(4) of the Act.

Comment: A few commenters supported CMS' decision to exclude value-based purchasing arrangements from the ASP bundled arrangement definition, citing this decision reflects structural differences between ASP and MDRP frameworks. Specifically, while manufacturers can revise pricing data to address time-based bundled discounts in MDRP, the ASP framework lacks a routine process for retrospective payment adjustments.

Response: We thank the commenters for their support.

Comment: A few commenters opposed CMS' proposal to not adopt the portion of the Medicaid definition of bundled sale stating that value-based purchasing arrangements may qualify as a bundled sale. These commenters recommend CMS adopt a consistent approach in the context of ASP.

Response: We believe not adopting this definition at this time provides the agency the opportunity to monitor and assess how such a definition may affect ASP, especially as we intend to finalize mandatory submission of reasonable assumptions.

Comment: A commenter noted that the most likely type of bundle is a temporal or cross period bundle, thus the commenter urged temporal bundles should not be considered bundled arrangements for purposes of calculating ASP. Rather, price concessions in one period that are based on a purchase or performance requirement in a different period should be handled as a lagged eligible price concession.

Response: We will consider this suggestion as we continue to refine this policy area.

After consideration of public comments, we are finalizing as proposed to not adopt the portion of the Medicaid definition of bundled sale stating that value-based purchasing arrangements may qualify as a bundled sale.

Comment: We received one out-of-scope comment. In this comment, MedPAC encouraged CMS to monitor the issue of bundled price concessions in the context of products without an alternative, citing concerns in which manufacturers could use the bundle discount to pressure buyers into also purchasing a second product that does have competition.

Response: We consider this issue to be outside the scope of the proposed rule; however, we will take it under consideration for potential future rulemaking.

c. Bona fide service fees

As described previously in the background section, currently, the term "BFSFs" means fees paid by a manufacturer to an entity, that (1) represent FMV (2) for a bona fide, itemized service actually performed on behalf of the manufacturer (3) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (4) that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.[142] A fee must meet all four conditions of the definition to be considered a BFSF rather than a price concession to be deducted from

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[142] 42 CFR 414.802.

ASP. For these reasons, in this proposed rule, we are proposing policies to provide additional guidance on two aspects of the calculation of manufacturer's ASP. First, we are proposing regulatory text to specify when certain fees are considered price concessions and on how manufacturers should allocate pricing for drugs sold under a bundled arrangement. Second, we are proposing to revise the definition of BFSFs by (1) specifying the methodology that should be used to determine FMV and the time period after which manufacturers should reassess the FMV; and (2) further explaining what we consider to be sufficient evidence of whether or not a fee is passed on in whole or in part to an affiliate, client, or customer of an entity. We are also proposing that in the absence of specific guidance, manufacturers be required to submit any reasonable assumptions they utilize for manufacturer's ASP calculations (which is currently voluntary), including documentation of the methodology used to determine fair market value and

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(1) Fair Market Value

One element of the definition of BFSFs specifies that the fees must represent FMV for the service. To date, we have not issued guidance on a specific method that manufacturers must use to determine whether a fee represents FMV. In the CY 2007 PFS final rule (71 FR 69666 through 69670), we stated that the appropriate method or methods for determining whether a fee represents FMV may depend upon the specifics of the contracting terms, such as the activities the entity will perform and the agreed-upon mechanism for establishing the payment (for example, percentage of goods purchased). We stated in that final rule that we believe manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining FMV of drug distribution services for which they contract. Therefore, we did not mandate the specific method manufacturers must use to determine whether a fee represents FMV for purposes of excluding BFSFs from the calculation of ASP.

As discussed previously in the background section, the December 2022 OIG report identified BFSFs as an area where CMS could provide additional guidance to manufacturers and further stated that manufacturers expressed that competitors may be taking disparate approaches when applying CMS' four-part test to make these determinations. In some cases, service fees that are very high could mask price concessions that are passed on by the entity performing some bona fide services so that the product's ASP can remain high. Conversely, certain fees that should be classified as BFSFs could be incorrectly

classified as a price concession to reduce the manufacturer's ASP and mask price increases that could be faster than the rate of inflation for purposes of the Medicare Prescription Drug Inflation Rebate Program. Consequently, we recommended additional guardrails to ensure that BFSFs are correctly classified, and that the manufacturer's ASP is not manipulated to be artificially increased or decreased.

Accordingly, we (1) proposed revisions to the definition of BFSFs at § 414.802 that retains the existing four prong test (as described in the background section) and adds proposed requirements for the standards and the methodology that should be used to determine the FMV for such fees; (2) the time period after which manufacturers should reassess the FMV; and (3) any FMV analysis of fees that vary directly with the amount of drug sold or price of a manufacturer's drug must be conducted by an independent third party that does not have a conflict of interest.

Based on the structure or arrangement of certain fees that meet the definition of BFSF, we proposed additional requirements for the standards and methodology that should be used to determine FMV. Specifically, we proposed that for fees paid by a manufacturer to an entity that do not vary directly with the amount of drug sold or price of a manufacturer's drug, that the FMV must be determined either based on comparable market transactions that generally reflect current market conditions or the cost of the service plus a reasonable markup to the total cost.

We proposed that, for fees paid by a manufacturer to an entity that vary directly with the amount of drug sold or price of a manufacturer's drug, the FMV must be determined by using the cost of the service and adding a reasonable markup to the total cost. If any material portion of cost data is not available, manufacturers should follow a market-based approach based on verifiable market data until such time as sufficient cost data becomes available. In addition, we proposed that under such circumstances that the FMV assessment must be conducted by an independent third-party valuator. This means that the valuator must not have any financial relationship (other than the arrangement to conduct FMV analyses) with either party to the arrangement and no stake in the outcome of the valuation. The FMV analysis must be documented with a clear explanation, including a description of the methodology used.

Regarding FMV assessments, we proposed manufacturers conduct periodic updates of any FMV analyses for service arrangements that are ongoing, at a frequency no less than the renewal frequency of

the agreement (that is, annually for annual renewals). We stated that documentation of this update should be included in the reasonable assumption documentation that corresponds with the quarter when the update is conducted. We agreed that implementing standards and defining the methodology manufacturers must use to determine FMV would better establish uniform industry practices and provide the desired clarity requested by manufacturers in the December 2022 OIG report.

The following is a summary of the comments we received and our responses.

Comment: A few commenters stated support for enhanced guidance, accountability, and transparency for BFSFs, and affirmed support for ensuring the accurate calculation of FMV.

Response: We thank the commenters for their support.

Comment: Many commenters did not agree with CMS' proposed FMV standards and methodology, arguing the rule overemphasizes cost-based methods and limits flexibility. They stated that CMS should allow multiple valuation approaches (cost-, market-, income-based, or hybrid) to reflect market realities and maintain that well-documented service fees should not be presumed price concessions.

Some commenters stated that the current FMV framework is adequate and that the proposal departs from longstanding CMS policy and industry practice. They cited past rulemaking (for example, 2016 MDRP, 2007 PFS) supporting manufacturer discretion and noted limited industry demand for additional FMV guidance in the December 2022 OIG report.

Several commenters stated that CMS' proposed definition of BFSFs exceeds its statutory authority and diverges from ASP/AMP alignment. They contended that percentage-based fees are not inherently improper and that rigid formulas conflict with existing standards under Stark and Anti-Kickback Statute (AKS). A commenter suggested aligning percentage-based fees with existing precedents, such as the GPO safe harbor to the AKS at 42 C.F.R. § 1001.952(j). -.

Others noted the new BFSF test adds regulatory burden and that extending the no pass-through requirement to "affiliates" is overly broad, ambiguous, and unauthorized. They noted that unclear definitions could disrupt legitimate business arrangements and conflict with MDRP treatment of affiliates.

Response: We agree that it would be time-intensive to implement a new FMV methodology under the proposed timeline. We acknowledge commenters' concern about extending the no pass-through

requirement to "affiliates" and would like to further engage with manufacturers regarding determination of FMV that could address these concerns while also achieving the goal of accuracy and transparency when classifying costs for the calculation of ASP. As such, we are not finalizing the proposed requirements for the standards and methodology that should be used to determine FMV in this final rule. However, we encourage manufacturers to document in their reasonable assumptions which service fees are tied to costs that do not depend on the drug's price or volume and which service fees do. As we plan to engage with manufacturers , this information will aid with informing future policy development.

For comments noting the proposed FMV methodology requirements depart from established CMS policy, we recognize that this marks a shift from prior policy interpretation. However, as new services enter the market, policy updates are occasionally required to ensure appropriate regulation and oversight. We also take recommendations outlined in OIG reports seriously and are committed to addressing them effectively.

We also acknowledge commenters' other concerns, including whether we have the statutory authority to impose BFSF standards that conflict with MDRP and the FMV requirements conflict with FMV frameworks under other law in our purview. In light of these comments, we intend to continue to evaluate and consider this issue in next year's rulemaking cycle. We also recognize that although this proposal would impose an additional regulatory burden on manufacturers, we anticipate that it would support the Administration's priorities of increased transparency and potentially lower drug prices.

Further, we appreciate commenters' feedback regarding the exclusion of the term "affiliates" and will further consider whether to incorporate this term in future rulemaking.

Finally, we agree with commenters about limiting the scope of the BFSF analysis to fees directly tied to drug sales. We will use information from manufacturers' reasonable assumption to inform future policy development concerning whether a flexible FMV approach is appropriate and to evaluate whether certain fees exceed FMV.

Comment: A commenter stated concerns about pharmacy benefit managers (PBMs), group purchasing organizations (GPOs), and related fee reform, citing the proposed rule allows these intermediaries to demand or require payments directly linked to drug costs.

Response: These issues fall outside the scope of the proposed CMS BFSF rule as the proposed rule does not directly regulate PBMs or GPOs.

Comment: A commenter stated support for the proposed frequency of FMV determinations and submission of FMV assessments, affirming that these requirements would give CMS increased visibility into how ASP is calculated and greater ability to monitor differences in approaches across manufacturers and the potential need for future guidance.

Response: We thank the commenters for their support.

Comment: Several commenters did not agree with the proposed requirement for manufacturers to conduct periodic updates of FMV. They cited ambiguities regarding both the scope and frequency of the reassessments. Commenters noted that FMV reassessment is unduly burdensome due to the complexity of the process, which requires reviewing detailed contract terms, compiling and analyzing historical and projected data, and engaging in multiple rounds of consultation to clarify service scope and pricing structures. Given that many contracts are short-term in nature, commenters stated that requiring a new FMV analysis upon every renewal could introduce unnecessary inefficiencies without meaningfully improving compliance or accuracy.

Several commenters requested at a minimum the FMV reassessment for ongoing service arrangements needs more flexibility. For example, manufacturers could rely on FMV ranges established by third party evaluators for common service types to ensure fees remain within an inflation-adjusted FMV range. They also could apply existing FMV assessments to new contracts involving similar services and vendors for a reasonable period of time (for example, – 3 to 5 years), unless there is a material change in the scope or costs of the services provided or a significant shift in market conditions. Another commenter suggested that FMV reassessments need not be conducted for minor contract modifications and not more than once every 3 years. Furthermore, a commenter suggested allowing manufacturers to submit summary information in the form of reasonable assumptions regarding their approach to determine FMV.

Response: We agree that manufacturers should provide summary information on FMV assessments as part of their reasonable assumptions, as we are finalizing that portion of the proposal. We will use reasonable assumptions to better understand the scope and frequency of FMV reassessments, and

this information will aid with informing future policy development. As such, we are not finalizing the proposal that manufacturers reassess FMV upon contract renewal in this final rule.

Comment: A few commenters supported the requirement that the FMV assessment must be conducted by an independent third party for percentage-based fees.

Response: We thank the commenters for their support.

Comment: Many commenters did not agree with the requirement that manufacturers obtain independent third-party FMV assessments for BFSFs. They stated that the terms "independent" and "financial relationship" are not defined, which could result in an overly broad and unintended interpretation. Commenters further expressed concern that the proposal might disqualify accounting, actuarial, and transfer pricing firms with which manufacturers already maintain business relationships. Collectively, commenters stated that, as drafted, the proposal could significantly reduce the number of firms with experience in pharmaceutical FMV assessments, thereby causing delays. Additionally, commenters noted that requiring third-party assessments for every agreement could substantially increase compliance costs, while also incentivizing valuators to demand shorter contract terms and higher fees.

Several commenters requested that CMS clarify the criteria by which an FMV evaluator would be considered "independent". Other comments requested alternatives to the FMV evaluator. For example, CMS could require personnel conducting valuations to exercise independent judgment, supported by mechanisms such as ethical screens between teams or that CMS allow manufacturers to identify independent third-party verification services. Another commenter requested CMS authorize established vendors with subject matter expertise to conduct FMV assessments. Lastly, a commenter requested CMS allow FMV reassessment to be conducted internally by applying an inflation adjustment to the valuation.

Response: We are persuaded by these comments that more information is needed to determine which parties may determine FMV and if there are circumstances in which an internal determination may be appropriate. We will engage with interested parties to better understand these issues and consider them in future rulemaking.

After consideration of public comments, we are not finalizing the proposed language regarding FMV methodology standards, FMV reassessments, and independent third-party valuator requirement. We

will engage with interested parties to better understand current practices and challenges related to FMV methodologies, reassessments, and the use of third-party valuators.

(2) Fees Presumed to be Price Concessions

We proposed revisions to § 414.804(a)(2) to specify when certain fees should be presumed to be price concessions. Specifically, we proposed that if fees paid by a manufacturer to an entity vary directly with the amount or price of a manufacturer's drugs (that is, the fees paid are (1) percentage-based fees or (2) flat fees or fixed fees that are designed in such a way as to approximate percentage-based fees), such fees are presumed to be price concessions to be deducted from the calculation of the manufacturer's ASP unless such manufacturer determines such fees to be FMV using a cost-based approach which may be further validated with market-based data.

The following is a summary of the comments we received and our responses.

Comment: A few commenters did not agree with the proposal to presume that certain fee arrangements do not qualify as BFSFs. They noted that percentage-based fees are widely used across the pharmaceutical supply chain and highlighted the Congress's explicit recognition of percentage-based BFSFs in the context of AMP reporting. They further cited that in amending the AMP definition, the Congress provided examples of fees it considered to be BFSFs that should be excluded from AMP calculations, and those examples clearly encompass percentage-based fees. Furthermore, commenters stated that this presumption would result in the under-exclusion of BFSFs ASP calculations.

Other commenters requested clarification that only those service fees which reduce the acquisition cost for a purchaser should be treated as price concessions. They claimed that what is relevant is whether the arrangement ultimately lowers the price paid by the provider who will be reimbursed based on the product's ASP.

Response: We will take these comments and the related issues under consideration in future rulemaking.

After consideration of public comments, we are not finalizing the proposed regulatory text to specify when fees are presumed to be price concessions.

(3) Evidence

Another element of the BFSF definition specifies that the BFSF must not be passed on, in whole or in part, to a client or customer of an entity. When finalizing the CY 2007 PFS final rule (71 FR 69669 through 69670), we stated that there may be significant barriers that limit a manufacturer's ability to determine whether a fee that otherwise meets the definition of BFSF is passed on, in whole or in part, to a client or customer of any entity. We noted in the preamble section of that rule that we believe that it is essential to retain the "not passed on" element in the definition of BFSFs given that the "not passed on" element is a key factor in distinguishing a price concession from a BFSF because, if a fee that is passed on is excluded from the ASP calculation, then there is a greater risk of the ASP being inappropriately inflated. We stated that if a manufacturer has determined that a fee paid meets the other elements of the definition of "bona fide service fees," then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.

There may be certain fees that a manufacturer classifies as BFSFs for the purposes of calculating the manufacturer's ASP that should actually be considered price concessions and, therefore, deducted from the manufacturer's ASP. In the December 2022 OIG report, manufacturers reported inconsistent practices in the treatment of BFSFs. As such, we proposed that it is no longer appropriate that a manufacturer may presume, in absence of any evidence or notice to the contrary, that a fee paid is not passed on to an affiliate, client, or customer of any entity. This proposed revision to the definition specified that, in addition to a client or customer of any entity, that the fee also shall not be passed on to an affiliate, which means an affiliate of an entity that is receiving the fee is providing the service. We proposed the addition of the word affiliate to more comprehensively address the type of arrangements that may exist between certain entities.

In addition, we proposed that the manufacturer be responsible for obtaining a certification or warranty from the entity receiving the fee stating that such fee will not be passed on to an affiliate, client, or customer of any entity. We proposed to add new § 414.804(a)(5)(iii) requiring manufacturers to provide certification letters from any recipient of a BFSF that the fee is not passed on in whole or in part to an affiliate, client or customer of an entity, whether or not the entity takes title to the drug.

We also proposed to revise § 414.804(a)(5) to add additional data submission requirements. This paragraph currently states that the manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter. We proposed to add a header to this section titled "Submission Requirements" and remove "The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter." We proposed to add three paragraphs (i, ii, and iii). The proposed text would be revised to state that manufacturers must submit the following to CMS within 30 days of the close of the quarter:

- The manufacturer's average sales price, which must be calculated by the manufacturer every calendar quarter. The first quarter submission must be submitted by April 30, 2004.
- Effective January 1, 2026, reasonable assumptions for calculation of the manufacturer's ASP including the fair market value analysis for bona fide service fees, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices, including documentation of the methodology used to determine fair market value and periodic reviews of fair market value.
- Effective January 1, 2026, certification letter from the recipient of a bona fide service fee (as defined under § 414.802) as evidence that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity, whether the entity takes title to the drug.

We stated that, these data submission requirements, if finalized, would be effective for sales occurring on or after January 1, 2026, and that data would be due to CMS by April 30, 2026, and used in the July 2026 Medicare Part B Drug Payment Limit File. The newly proposed certification letter would be submitted in the current reporting portal and uploaded under reasonable assumptions. Lastly, we explained that manufacturers must maintain and submit to CMS a copy of the FMV analysis, confirming it was conducted in a timely manner, documentation (such as a certification letter from the recipient of the fee) that the fee is not passed on in whole or in part to an affiliate, client or customer of an entity, whether or not the entity takes title to the drug, and documentation (such as a mutual representation in the relevant

services agreement) that both parties have agreed to represent the payment as a BFSF in a consistent manner to all third parties, including any affiliates, clients, and governmental agencies.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported mandatory submission of reasonable assumption letters. A commenter encourages CMS to read these closely and provide feedback on them for purposes of driving greater consistency. The commenter requests CMS confirm that reasonable assumptions letters are covered by the "Confidentiality" provision in the ASP statute. The commenter further requested CMS should also confirm that it will treat these reasonable assumptions as confidential and proprietary financial information within the meaning of the Freedom of Information Act (FOIA), the relevant Federal criminal statute, the FOIA regulations, and other applicable laws, regulations, or policies. Specifically, this information is subject to exemption from mandatory disclosure under Exemption of FOIA across manufacturers in the calculation and interpretation of ASP.

Response: We agree that these submissions are an important tool for promoting transparency, consistency, and accuracy in ASP reporting. As noted above, we intend to review reasonable assumptions, and if any concerns are identified, we will reach out to the manufacturer. Regarding confidentiality, data collected through the ASP module will be protected from disclosure to the extent required by the law. We cannot release information about specific manufacturers or wholesalers or prices charged by such manufacturer or wholesaler for specific products due to statutory confidentiality provisions that limit the release of ASP data as specified in section 1847A(f)(2)(D) of the Act, and in section 1927(b)(3)(D) of the Act.[143]

Comment: A commenter did not agree with the mandatory submission of ASP reasonable assumption letters and recommended CMS maintain the practice of voluntary submission of reasonable assumptions and stated that if CMS is concerned with variances in reasonable assumptions then CMS should standardize a template.

Response: We do not agree with the commenter and believe that mandatory submission of ASP reasonable assumption letters is necessary to enhance transparency, promote consistent application of

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[143] Average Sales Price (ASP) Quarterly Publication Process, Centers for Medicare and Medicaid Services. January 17, 2025. https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.

ASP methodologies, and strengthen program oversight. Although there is not currently a standardized format for reasonable assumption letters, as the commenter noted, there is a template form under review with PRA.

Comment: Several commenters did not agree with the proposal that manufacturers provide documentation of the methodology used to determine FMV. Commenters cited concerns with the administrative and financial burden that quarterly FMV submissions would impose on manufacturers and added that this requirement contradicts the Administration's stated aim of reducing unnecessary paperwork. A few commenters noted that FMV analyses involve proprietary valuation methods, market data, and sensitive business strategies not meant for disclosure. A few commenters highlighted the absence of corresponding regulatory text to codify the preamble's proposals, which could lead to confusion and inconsistencies. Finally, another commenter stated the FMV documentation requirement provides no clear benefit to the healthcare system.

Response: We do not believe that the requirement to document FMV determinations will impose an undue burden on manufacturers. Manufacturers should already maintain sufficient internal documentation to support their FMV assessments. To clarify, FMV documentation is not due quarterly; effective January 1, 2026, manufacturers must document the methodology used to determine FMV for all current, new, and renewed contracts. For example, all FMV determinations for current contracts are due by April 30, 2026 with their submission of ASP for first quarter of sales in 2026. If a service arrangement is newly signed or renewed between January 1, 2026 through March 31, 2026, the FMV determination data is also due by April 30, 2026. To minimize administrative burden, we will accept well-detailed summaries of FMV methodologies that clearly describe the data sources, assumptions, and rationale supporting the determination. While this would be an additional reporting requirement, this supports the Administration's priorities of lowering drug prices. Further, in reference to the statement that FMV data is proprietary, as we noted previously, data collected through the ASP module will be protected from disclosure to the extent required by law. Lastly, we do not agree that requiring FMV documentation does not provide a clear benefit to the healthcare system. This information can enhance transparency, accountability, and program integrity. Following publication of the final rule, we will provide a template of the reasonable assumptions letter for manufacturers to document FMV analyses.

Comment: A few commenters recommended modifications to the FMV documentation requirement to reduce administrative burden. A commenter suggested that CMS require manufacturers to maintain FMV documentation supporting BFSFs, consistent with existing MDRP guidance that requires manufacturers to retain records for 10 years from the date of reporting the BFSF to CMS. Commenters stated that this approach would minimize paperwork while preserving CMS' ability to request and review FMV analyses as necessary. Another commenter requested that CMS adopt a flexible approach in its review of FMV documentation and operate under the presumption that manufacturers are complying in good faith.

Response: We do not agree with the commenters' suggestion to require manufacturers only to maintain, rather than submit, FMV documentation. We believe that requiring submission promotes greater transparency and consistency across manufacturers and enables us to conduct more effective oversight of FMV determinations. Regarding the suggestion we adopt a flexible approach in its review of FMV documentation, because we did not propose a policy for CMS's review of reasonable assumptions, this comment is out of scope. We will review reasonable assumptions to inform future policy development. However, if we determine that a manufacturer has misrepresented information in the reporting of its ASP, we may refer the issue to HHS's Office of Inspector General (OIG) to determine whether a civil monetary penalty should be imposed, in accordance with section 1847A(d)(4) of the Act.

Comment: Many commenters did not agree with CMS' proposed certification requirement for BFSFs. Commenters stated that the change would impose substantial administrative, contractual, and operational burdens on manufacturers, who often manage hundreds of service agreements. They emphasized that manufacturers cannot compel third-party vendors to provide certifications, which risks misclassifying legitimate BFSFs as price concessions. Commenters further questioned CMS' legal authority to impose this obligation, stating it is inconsistent with existing statutory frameworks, Medicaid rules, and longstanding CMS policy that presumes BFSFs are not passed on. Many highlighted that the proposal undermines the Administration's stated goal of reducing regulatory burden and paperwork.

Response: We do not agree that the required certification would add substantive burden. This measure targets transparency and is not a fundamental change in how manufacturers calculate FMV. The certification ensures accountability and documentation that payments reported as BFSFs are consistent

with regulatory definitions. Until we observe evidence that service providers are unwilling to provide such certifications, we do not find these concerns to be substantiated. Finally, while this proposal adds some additional regulatory and paperwork requirements, it supports the Administration's priorities to lower drug prices and increase transparency.

After consideration of public comments, we are finalizing as proposed to require manufacturers submit reasonable assumptions including documentation of the methodology used to determine FMV for current, new, and renewed contracts. We are also finalizing as proposed to require certification letters from the recipient of a BFSF for prospective contracts that the fee is not passed on in whole or in part to a client or customer of the recipient of the fee, whether or not the entity takes title to the drug.

(3) Further Guidance on the BFSF Definition

In the CY 2007 PFS final rule (71 FR 69667 through 69668), we discussed the option of providing a list of bona fide services. However, many commenters at that time were opposed to establishing a list of bona fide services because it would require ongoing refinement for manufacturers to accurately calculate ASP. In that final rule, we did not establish a list of bona fide services because we wanted to avoid inadvertently limiting the scope of what could constitute a bona fide service. We believed that constructing an exhaustive list could be prohibitive over time. However, in the CY 2026 proposed rule we proposed some specific, non-exhaustive examples of fees and how they should be considered in the calculation of manufacturer's ASP for the following reasons.

First, we noted that certain payments by drug manufacturers to drug distributors, which lower the price that distributors and purchasing physicians pay, appear to be price concessions. In 2024, the Department of Justice filed a complaint against a manufacturer alleging the company engaged in fraudulent drug price reporting practices by classifying payments to distributors to cover credit card processing fees as BFSFs instead of price concessions.[144] The manufacturers' payment allegedly enabled the purchasers of the product to use credit cards to purchase drugs from the distributor without incurring an additional fee that would otherwise be charged, while also taking advantage of the benefits of using credit cards, such as "cash back" and other credit card rewards. This type of arrangement would lower

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[144] United States Files Complaint Against Regeneron Pharmaceuticals Alleging Fraudulent Drug Price Reporting, District of Massachusetts, United States Attorney's Office. April 2024. https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-regeneron-pharmaceuticals-alleging-fraudulent-drug.

the price of the drug to both the distributor and the distributors' customers, and the manufacturers' payments should be classified as price concessions, which are deducted from ASP, not BFSFs.

Second, as discussed in our Autologous Cell-based Immunotherapy and Gene Therapy Payment proposal, we also proposed that any payment by the manufacturer to an entity for tissue procurement is not considered a BFSF for the purposes of calculating the manufacturer's ASP since this is an integral part of the manufacturing process for autologous cell-based immunotherapy or gene therapy and should be included in the price of the product.

Third, certain fees for data sharing services about the product appeared to exceed the FMV for the service or were not for bona fide services because the data is required for legal compliance and audit purposes under the services agreement (such as complete and timely data to validate that a rebate or discount has been earned or is not duplicative prior to its payment by the manufacturer). If a manufacturer pays an entity for providing data back to the manufacturer about the product being sold, that fee should be assessed for FMV as discussed previously in this section and we proposed a certification or warranty from the entity providing the service that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity. As discussed previously in this section, we proposed that such certification or warranty should be submitted by the manufacturer to CMS as part of the quarterly ASP data submission.

Lastly, certain fees paid for distribution services appeared to exceed the FMV for the service. Similar to data sharing services, if a manufacturer pays an entity for distributing their product, the fee should be assessed for FMV, and we proposed a certification or warranty should be provided by the entity providing the service that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity. As discussed previously in this section, we proposed that such certification or warranty should be submitted by the manufacturer to CMS as part of the quarterly ASP data submission.

The following is a summary of the comments we received and our responses.

Comment: Many commenters did not agree with CMS' proposed non-exhaustive list of excluded fees, saying the list is confusing and ambiguous, creates uncertainty and compliance risks, and could reduce provider reimbursement. Commenters did not agree with CMS' characterization that certain data sharing and distributor service fees are not BFSFs. They cited that the Congress explicitly excluded

distribution and inventory management fees from AMP, suggesting they are not price concessions, and therefore, CMS is overreaching by reclassifying them. Commenters requested that CMS identify specific problematic fees, solicit input through targeted questions, and issue clear guidance to avoid confusion. Commenters also object to the inclusion of credit card processing fees as an example, noting that CMS has not provided sufficient justification for excluding them. A commenter does not believe that an isolated example of credit card processing fees is sufficient justification for providing the list.

Response: We do not agree that we have not provided sufficient justification for excluding credit card fees to distributors as BFSFs, as described in the proposed rule. However, we are persuaded by some of the commenters' concerns that providing examples of fees could have unintended implications and are not finalizing a list of example of fees at this time.

After consideration of public comments, we are not finalizing the list of fee examples and how they should be considered in the calculation of manufacturer's ASP.

Comment: Many commenters expressed concern regarding CMS' proposed implementation of January 1, 2026 for the BFSF proposals, asserting that the proposed timeline is too aggressive and does not allow sufficient time for interested parties to adjust. Commenters highlighted the extensive contract renegotiations, valuations, system updates, and compliance procedures required. Commenters stated concerns with the rushed timeline, including reporting inconsistencies, compliance risks, and administrative inefficiencies, potentially exposing manufacturers to audits and penalties. Commenters requested more time for CMS to fully evaluate operational and policy implications, conduct additional engagement and analysis, and ensure that the rulemaking does not result in unintended consequences. Some commenters recommended that, if finalized, the policy should apply only to new contracts moving forward.

Response: We agree with commenters that the proposed implementation timeline for the BFSF definition proposals does not provide sufficient time for manufacturers to make the necessary system and operational changes. Accordingly, we intend to address this policy area in rulemaking next year. To clarify, the proposed certification requirement applies to new contracts. However, documentation of the FMV methodology applies to current as well as new contracts. As stated previously, manufacturers are expected to document and submit the FMV methodology used for any current BFSF arrangements by

April 30, 2026 (that is, the due date for ASP data submission to us for sales occurring in the first quarter of CY 2026) and reflected in the July 2026 Medicare Part B Drug Payment Limit File.

Comment: Many commenters recommended CMS conduct additional research and create more opportunities for dialogue between interested parties before implementation. Commenters noted CMS could host listening sessions, establish a technical advisory panel to work with providers and interested parties and develop technical guidance, or conduct a survey of manufacturer practices.

Response: Thank you for this feedback and methods of future engagement.

Comment: A few commenters did not agree with the proposal because there is no regulatory impact analysis assessing the costs associated with the proposed changes. A commenter requested that CMS withdraw BFSF proposal and produce an analysis showing costs and benefits of changing the FMV methodology. A commenter requested a two-pronged approach: (1) conduct a comprehensive study of BFSF impacts on ASP before rulemaking, considering scenarios where fees increase or decrease ASP, treatment discrepancies, contract timelines, potential drug shortages, and interactions with other legislative/regulatory actions; (2) determine whether changes should apply universally or in a more targeted manner.

Response: We do not agree that a separate regulatory impact analysis or additional study is necessary. We believe that engaging directly with manufacturers and reviewing reasonable assumptions letters provides sufficient information to assess current practices and inform policy decisions.

Comment: We received a few comments outside the scope of the proposed rule. A commenter requested that CMS convene a public-private interested parties' group to develop recommendations for comprehensively reforming Part B drug payments to align payment to services provided and outcomes achieved versus the cost of the drug. Another commenter requested CMS gather physician costs on drugs where payment is reported to be below or less than allowed 6 percent and recommended CMS review the costs associated with administering drugs in the office where ASP is less than five percent above acquisition price or where ASP does not meet acquisition price.

Response: We note that the recommendations are outside the scope of this rulemaking.

d. Summary

In summary, we are finalizing a definition of bundled arrangement at § 414.802 with the removal of the

phrases of purchasing patterns and prior purchases and amending § 414.804(a)(2) with new paragraphs (iii) and (iv) as proposed to provide guidance to manufacturers regarding pricing of bundled price concessions. We are not finalizing the proposed new regulatory text at § 414.804(a)(2)(i) to specify when certain fees are considered price concessions. We are not finalizing the proposed revised definition of BFSFs at § 414.802. We are finalizing the revisions at § 414.804(a)(5) to update requirements for ASP data submissions as they relate to reasonable assumptions letters, FMV documentation for current, new, and renewed contracts in reasonable assumption letters, and evidence that BFSFs are not passed on with some modifications in (ii) and (iii). Finally, we are not finalizing a non-exhaustive list of certain fees that we either do not consider BFSFs or may not be in line with FMV.

3. Average Sales Price: Units Sold at Maximum Fair Price

The Act establishes the Medicare Drug Price Negotiation Program (the "Negotiation Program") to negotiate a maximum fair price (MFP)[145] for certain high expenditure, single source drugs payable under Medicare Part B and covered under Part D (each, a "selected drug"). For the initial price applicability year 2026, CMS reached agreement on a negotiated price for all 10 selected drugs covered under Part D. Then, for initial price applicability year 2027, CMS selected an additional 15 drugs covered under Part D. For the third year of the Negotiation Program, initial price applicability year 2028, CMS will select for negotiation up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D.

Beginning in initial price applicability year 2028, for selected drugs payable under Part B, section 1847A(b)(1)(B) of the Act sets the Medicare Part B payment limit during the price applicability period as 106 percent of MFP. Payment limits are published on the Medicare Part B Drug Payment Limit File, which is updated quarterly. For selected drugs with a negotiated price for initial price applicability year 2026 and 2027 that have utilization under Medicare Part B, we clarify that the Part B payment limit will not be based on the MFP unless it is selected for renegotiation, pursuant to section 1194(f)(3) of the Act and as discussed in section 130.2 of the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of sections 1191 through 1198 of the Act for Initial Price Applicability Year 2028 and

[145] Defined at section 1191(c)(3) of the Act.

Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028[146]; and there is an agreed-upon renegotiated MFP. We note that the guidance was updated on September 30, 2025; however, there were no changes to this policy in section 130.2.[147]

Manufacturers of drugs payable under Part B are required to report the manufacturer's ASP to CMS each quarter as described in sections 1927(b)(3) and 1847A(f) of the Act, even when a drug is a selected drug with an MFP, including a renegotiated MFP. The statute directs that the manufacturer's ASP include sales to all purchasers in the United States (section 1847A(c)(1) of the Act) with two exempted categories of sales: (1) sales exempt from best price under section 1927(c)(1)(C)(i) of the Act; and (2) sales that are merely nominal in amount as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, as limited by section 1927(c)(1)(D) of the Act. Units of drugs sold at MFP do not fall in either of those categories. In addition, units sold at MFP are expressly included in the determination of best price, as stated in section 1927(c)(1)(C)(ii)(V) of the Act. Therefore, since the statutory language does not expressly or implicitly exempt units of Medicare Part B or Part D MFP sales from the calculation of the manufacturer's ASP, we clarified in the CY 2026 PFS proposed rule (90 FR 32545 through 32546) that units of selected drugs sold at MFP are included in the calculation of the manufacturer's ASP described in section 1847A(c) of the Act effective January 1, 2026.

The file used for publishing payment limits for drugs covered under Part B has commonly been referred to as the "ASP drug pricing file" likely because most drugs listed on the file have a payment limit based on the ASP (usually 106 percent of ASP). However, the file also contains the payment limits based on other pricing metrics. For example, several provisions in section 1847A of the Act require that the payment limit be based on a pricing metric other than ASP under specific circumstances, including the following:

- When the Wholesale acquisition cost (WAC) is less than ASP for a single source drug or biological (section 1847A(b)(4) of the Act);
- When ASP exceeds the widely available market price (WAMP) or average manufacturer price (AMP) (section 1847A(d)(3)(C) of the Act); and

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[146] See: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.
[147] See: www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

- For a selected drug, 106 percent of MFP (section 1847A(b)(1)(B) of the Act).

In such circumstances, only the actual payment limit is published on the file (and no ASP information is displayed). Therefore, we now refer to it as the Medicare Part B Drug Payment Limit File.

While we did not make a proposal or solicit comments on the policy statement clarifying that (1) units of selected Part B or Part D drugs sold at the MFP are included in the manufacturer's ASP and (2) when the Medicare payment limit is based on MFP, the Medicare Part B Drug Payment Limit File will display the MFP-based payment limit, we received comments. Commenters mentioned statutory framework and its relationship to ASP, AMP, and best price; operational and reporting considerations; the role and publication of ASP values in CMS files; and potential implications across Medicare fee-for-service, Medicare Advantage, Medicaid, and commercial arrangements. Submissions also discussed biosimilar market dynamics, inflation-rebate calculations, and transparency and labeling in public files. We appreciate the thoughtful and robust feedback on this policy statement.

4. Autologous Cell-based Immunotherapy and Gene Therapy Payment

a. Background

Medicare Part B covers many cellular immunotherapies and gene therapies that are FDA-approved under a biologics license application (BLA) as incident to drugs and biologicals under section 1861(s)(2) of the Act, which are paid under section 1847A of the Act (typically, at ASP plus 6 percent). Cell-based autologous therapies are a particular subset, which require cells to be collected from the patient, altered to create the intended therapy, and then administered to the same patient for treatment of a condition. These steps generally include cell collection from the patient via apheresis (including leukapheresis), surgical removal, biopsies or other means, the cells are immediately transported at very low temperatures to a manufacturing site for genetic engineering and/or other steps (for example, activation, cell expansion, and/or quality testing). After the manufacturing steps are complete, the final product is transported back to the healthcare provider or treatment facility to be administered to the patient.

For example, for Chimeric Antigen Receptor (CAR) T-cell therapy, T-cells are collected from the patient via leukapheresis and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the same

patient to attack certain cancerous cells. For other autologous cell-based therapy, the preparatory and manufacturing steps follow a similar general process.

Many studies show that the manufacturing steps for these therapies have a very high cost of goods sold (COGS), including very high proportion of labor costs in manufacturing, which ultimately leads to a high final cost of the therapy.[148,149] Some also note that the acquisition of raw materials, including tissue procurement, and quality-related activities are other top contributors to the COGS for autologous cell-based therapies. As technologies advance, there has been continued research to scale cell-based therapies, including a possible shift to allogeneic cell therapy, in which cell collection would be from healthy donors or stem cells. Manufacturing allogenic cell-based therapy would allow the therapy to be ready ahead of time instead of the multiple-week wait time between cell collection and administration of the treatment for allogeneic therapies.[150,151,152] Throughout research and discussions of cell-based therapies, tissue procurement is a key consideration in the discussion of the COGS. This further distinguishes all types of tissue procurement, whether it be for allogenic or autologous therapies, are part of the COGS and part of the manufacturing process for the products.

As technologies for autologous cell-based immunotherapies and gene therapies continue to advance, we aim for payment policies amongst these therapies to be consistent. Therefore, in the CY 2026 PFS proposed rule (90 FR 32546 through 32547), we proposed policies for how Medicare pays for the manufacturing steps across all types of autologous cell-based immunotherapies and gene therapies and proposed how these steps should be considered by manufacturers when submitting ASP data to CMS.

b. Payment

Medicare payment for the manufacturing steps to CAR T-cell therapies have previously been discussed in rulemaking, specifically in the CY 2019, 2020, and 2021 Medicare hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rules

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[148] Yonatan Y. Lipsitz, William D. Milligan, Ian Fitzpatrick, et al, A roadmap for cost-of-goods planning to guide economic production of cell therapy products, Cytotherapy,Volume 19, Issue 12, 2017, Pages 1383-1391.
[149] Brian Canter, Sabine Sussman, Stephen Colvill, Nitzan Arad, Elizabeth Staton, Arti Rai, Introducing biosimilar competition for cell and gene therapy products, *Journal of Law and the Biosciences*, Volume 11, Issue 2, July-December 2024, lsae015, https://doi.org/10.1093/jlb/lsae015.
[150] Caldwell KJ, Gottschalk S, Talleur AC. Allogeneic CAR Cell Therapy-More Than a Pipe Dream. Front Immunol. 2021 Jan 8;11:618427. doi: 10.3389/fimmu.2020.618427. PMID: 33488631; PMCID: PMC7821739.
[151] Abbasalizadeh, S., Pakzad, M., Cabral, J. M. S., & Baharvand, H. (2017). Allogeneic cell therapy manufacturing: process development technologies and facility design options. *Expert Opinion on Biological Therapy*, *17*(10), 1201–1219. https://doi.org/10.1080/14712598.2017.1354982.
[152] Pigeau GM, Csaszar E, Dulgar-Tulloch A. Commercial Scale Manufacturing of Allogeneic Cell Therapy. Front Med (Lausanne). 2018 Aug 22;5:233. doi: 10.3389/fmed.2018.00233. PMID: 30186836; PMCID: PMC6113399.

and the CY 2025 Physician Fee Schedule (PFS) final rule. In the 2019 OPPS/ASC final rule (83 FR 58904 through 58908), we finalized policies for payment of four Level III CPT codes (0537T through 0540T). We finalized that CPT codes describing (1) harvesting of blood-derived T lymphocytes, (2) preparation of T lymphocytes for transportation, cryopreservation, and storage, and (3) preparation of the CAR T-cell therapy for administration are not payable under OPPS. We stated that these codes describe various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. We noted that the billing and payment codes for the CAR T-cell therapies include leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals. In that final rule, we also finalized to pay separately for the Level III CPT code describing the administration service for CAR T-cell therapy. This policy was reiterated in the CY 2020 and 2021 OPPS/ASC final rules (84 FR 61231 through 61234 and 85 FR 85949 through 85951, respectively).

In September 2023, the CPT Editorial Panel deleted four Level III codes (0537T through 0540T) and created four new Level I codes (38225 through 38228) that describe only the steps of the complex CAR-T Therapy process performed and supervised by physicians: CPT code 38225 *(Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day)*; 38226 (*Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)*); 38227 (*Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration*); 38228 (*Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*). In the CY 2025 PFS final rule (89 FR 97779 through 97780), we finalized the policy to continue to bundle payment under the PFS for CAR-T services described under CPT codes 38225, 38226, and 38227. We stated that bundling payment is appropriate for these codes to align with OPPS policies to not pay separately for each step used to manufacture a drug or biological. In that final rule we also finalized to pay separately for CPT code 38228 (the service of CAR T-cell therapy administration), which aligns with OPPS policy.

To date, payment for procedures that are required for manufacturing other autologous cell-based immunotherapies and gene therapies (that are not CAR T-cell therapies) have not been explicitly

addressed. As discussed in the background section above, the tissue procurement step for all autologous cell-based therapies is a pivotal part of the manufacturing process and a key component of the overall cost of the product, that is, COGS. In addition, if certain therapies could be scaled in a way that they could be allogenic in nature, we see that the tissue procurement step would even more clearly be considered a manufacturing step.

We proposed that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself. The proposal would continue the current payment policies for CAR T-cell therapies and would extend the same payment policy to other autologous cell-based therapies. In our evaluation of each therapy, we noted there are similar sequences of steps as we described in the background section. Consistent with previous rulemaking, we proposed that Medicare not pay separately for each step used to manufacture an autologous cell-based immunotherapy or gene therapy. In other words, Medicare would not pay separately for the collection of raw materials or labor associated with the collection of raw materials for a drug or biological that are essentially part of the COGS. Payment for the raw materials and any labor associated with collection of the raw materials would be included in the payment of the drug or biological itself, using the billing and payment code for the product.

We solicited comments on the proposal to continue this policy for CAR T-cell therapies and extension of the policy to other autologous cell-based immunotherapy or gene therapy.

The following is a summary of public comments we received and our responses.

Comment: Some commenters supported including manufacturing-related costs in the payment for the product (that is, bundled payment) and recognizing manufacturer-paid procurement activities in pricing and reporting. They stated this approach reflects true acquisition costs, reduces uncompensated expenses, and aligns with current policy for CAR T-cell therapies.

Response: We thank the commenters for their support.

Comment: Many commenters did not agree with CMS' current payment policy for CAR T-cell therapies, under which services described by CPT codes 38225, 38226, and 38227 are bundled into the payment for the product, and the proposal to extend that approach to other autologous cell-based immunotherapy and gene therapy. They stated that preparatory procedures such as cell collection,

apheresis, laboratory processing, and dose preparation are clinician-ordered, resource-intensive, and medically necessary, and therefore should be reimbursed separately rather than treated as manufacturer COGS. Commenters further stated that the current bundling policy for CAR T-cell therapies oversimplifies the nature of cell and gene therapies, undervalues physicians' work (for example, clinical oversight and coordination), and is inconsistent with CMS' approach for stem cell transplants and other therapies in which analogous services are paid separately. Several commenters were concerned that continued bundling could worsen "underwater reimbursement," leading to practice closures, consolidation, and shifts to higher-cost inpatient settings or to integrated centers that can absorb unreimbursed costs, thereby increasing overall system costs.

Response: We appreciate commenters' feedback regarding the characterization of preparation services, such as cell collection by apheresis and local processing, for CAR T-cell therapies. Consistent with prior rulemaking under both the OPPS and the PFS—ranging from the CY 2019 OPPS/ASC final rule (83 FR 58904 through 58908) to the most recent CY 2025 OPPS/ASC final rule (89 FR 94080 through 94082) and the CY 2025 PFS final rule (89 FR 97778 through 97780)—we continue to view these services as integral preparatory steps in the manufacturing of the therapy and, therefore, included in the payment for the product. Medicare does not pay separately for each step used to manufacture a drug or biological product; these manufacturing-related services are accounted for in the drug payment code, while administration services are separately recognized.

We do not agree with commenters' comparisons to payment for stem cell transplant services and other therapies where collection and processing may be separately payable, as we do not consider those frameworks directly analogous to CAR T-cell therapies and other autologous cell-based immunotherapy and gene therapy products. In the stem cell transplant context, payment policies established under section 1886(d)(5)(M) of the Act and related implementing regulation at § 412.113(e) address clinical services furnished to the beneficiary and, in some cases, provide a distinct reasonable-cost cell-acquisition payment to subsection (d) hospitals. By contrast, for CAR T-cell therapies and other autologous cell-based immunotherapy and gene therapy paid under section 1847A of the Act, patient-specific collection and local processing are steps used to manufacture the labeled biological product and are reflected in the

product payment, while the administration service is separately payable. Maintaining this approach across payment systems promotes consistency in the treatment of these complex therapies.

Accordingly, we are finalizing that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself, consistent with the existing payment policy for CAR T-cell therapies. For concerns about potential payment adequacy, practice viability, and site-of-service shifts, we will continue to evaluate and monitor claims data, clinical practice patterns, and site-of-service trends to determine whether additional refinements may be warranted in future rulemaking.

Comment: Several commenters requested a clearer definition of "tissue procurement" and suggested that "cell collection" more accurately describes the procedures involved in autologous cell-based immunotherapy and gene therapy. They noted that "tissue procurement" is a broad term that could cause confusion, as it may encompass clinical activities (for example, diagnostic tissue biopsies) beyond those intended for payment and ASP reporting. Commenters also noted that, in some cases, a finalized CAR T-cell product is never administered to the beneficiary due to factors such as manufacturing failure or disease progression that may render the patient ineligible or result in death during the production period. They recommended complementary payment tools for preparatory procedure payment and requested clarification on how payment policy applies in these circumstances.

Response: We agree with commenters that "cell collection" is a more precise term than "tissue procurement" to describe the preparatory procedures such as apheresis or other collection of patient cells used as starting material for autologous cell-based immunotherapy and gene therapy, and we will adopt this terminology where appropriate for clarity. We further clarify that when the required procurement procedure does not involve apheresis (for example, when starting material is obtained via procedures including, but not limited to, surgical biopsy, tumor harvest, or tumor resection), the term "tissue procurement" remains appropriate in the context of manufacturing autologous cell-based immunotherapy and gene therapy. This clarification promotes consistent terminology and reporting and does not expand nor narrow existing payment scope. This finalized policy applies to patient-specific procurement and associated processing required by the product's manufacturing and release specifications. We thank commenters for providing their unique perspectives and experiences in situations where the

manufacturing process does not result in a final product being administered to a beneficiary and recommendation on complementary payment tools; these issues are out of scope for this final rule.

Comment: Several commenters requested CMS consider additional protections to ensure appropriate reimbursement for autologous cell immunotherapy and gene therapy services. They recommended mechanisms such as add-on codes for preparatory procedures and strengthened outlier protections under the OPPS to address cases with exceptionally high costs, including but not limited to severe toxicity-related hospital admissions. Commenters also noted that some hospitals may face unfunded costs such as anesthesia, intensive care unit readiness, registry reporting, and long-term monitoring, while community practices expressed concern about losing the ability to provide these therapies locally. A few commenters requested that CMS monitor ASP volatility in low-volume markets, where quarterly sales data may fluctuate significantly and create reimbursement uncertainty.

Response: As part of establishing the Part B payment limit based on the quarterly submission of all sales under section 1847A(c)(5) of the Act, we will continue to monitor pricing changes and patient volumes for autologous cell-based immunotherapies and gene therapies. For recommendations for additional protections such as add-on codes or enhanced outlier adjustments, this final rule addresses only (1) continuation of bundled payment for manufacturing steps under the PFS and OPPS and (2) the manufacturer-paid preparatory procedures for ASP reporting. These recommendations are therefore out of scope for this rule.

Comment: Many commenters did not agree with the assignment of PC/TC indicator "5" to CPT code 38228, which describes the administration of autologous CAR T-cell therapy. They stated that CAR T-cell administration should not be categorized as an "incident to" service and recommended revising the indicator from "5" to "0 (physician service)[153]," consistent with similar services such as autologous stem cell transplant infusion (CPT code 38241). Several commenters also requested that this correction be applied retroactively to January 1, 2025, and that CMS direct MACs to reprocess affected claims.

In addition, commenters objected to CMS' bundling of preparatory services described by CPT codes 38225 (cell collection), 38226 (cell processing/cryopreservation), and 38227 (receipt and dose preparation), which CMS has assigned status indicator "B" under both the OPPS and PFS, making them

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[153] https://www.cms.gov/status-indicators.

non-payable. They noted that this approach is inconsistent with CMS' payment policies for stem cell transplants, where collection and processing are separately reimbursed. Commenters recommended assigning status indicator "S" and place these codes in appropriate APCs to reflect the clinical complexity and resource intensity of these services.

Response: We made no specific proposal related to the CAR-T cell administration codes. Therefore, these comments are out of scope. Similarly, we did not propose changes to status indicators for CPT codes 38225 (cell collection), 38226 (cell processing/cryopreservation), and 38227 (receipt and dose preparation). As discussed above in this section, we are finalizing that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself, consistent with the existing payment policy for CAR T-cell therapies.

Comment: Several commenters requested clarification on how the policy would apply to allogeneic cell and gene therapies that require donor search, evaluation, and cell procurement. They explained that these steps—such as identifying and matching donors through national registries, performing compatibility testing, coordinating donor cell collection and transport, and monitoring donor health—are critical for patient and donor safety, can vary widely by case, and may occur even when the therapy is not ultimately administered. Commenters requested CMS to separately reimburse for these steps to reflect their complexity and variability. Alternatively, commenters requested for clarification whether these steps paid by manufacturers qualify as BFSFs.

Response: This rule addresses autologous cell-based immunotherapy and gene therapy manufacturing steps only. Policies specific to allogeneic donor procurement or transplant services are outside the scope of this rule. That said, as discussed earlier in this preamble, procurement of starting material—whether patient-derived (autologous) or donor-derived (allogeneic)—is integral to the manufacturing process and a component of a manufacturer's COGS. If, in the future, allogeneic therapies are scaled and a manufacturer makes payments to non-purchasing third parties for donor search, evaluation and cell procurement services, such payments may qualify as BFSFs and be excluded from ASP when they satisfy the four-part test at § 414.802. This final rule does not establish new payment policy specific to allogeneic donor search, evaluation, or cell procurement, nor does it alter existing

transplant-related procurement policies. We may consider whether additional clarification is warranted in future rulemaking as allogeneic cell-based therapy evolves.

Therefore, after consideration of public comments, we are finalizing as proposed to continue the existing payment policy for CAR T-cell therapies and to extend it to autologous cell-based immunotherapy and gene therapy. Under this policy, the costs of patient-specific cell or tissue procurement and processing remain bundled into the payment for the product.

c. Average Sales Price

Payment limit calculations for drugs payable under Part B are done on a quarterly basis using the manufacturer's ASP (as defined in § 414.902) using methodology in section 1847A of the Act. Manufacturers are required to report ASP data to CMS under sections 1847A(f)(2) and 1927(b)(3) of the Act. Manufacturers are instructed to calculate the manufacturer's ASP in accordance with section 1847A(c) of the Act and § 414.804(a). To date, we have not addressed how manufacturers of autologous cell-based immunotherapy or gene therapy should account for the procedures for the collection of cells used to manufacture the product into the calculation of the manufacturer's ASP.

As discussed in section III.A.3.a. of this final rule, the COGS and manufacturing process for an autologous cell-based immunotherapy or gene therapy include tissue procurement (that is, the collection of cells from the patient). Consistent with the proposal in the previous section that preparatory procedures required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself, we also proposed that, beginning January 1, 2026 (that is, data reflecting sales beginning on that date), any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that are paid by the manufacturer be included in the calculation of the manufacturer's ASP. We also proposed that any payment by the manufacturer to an entity for tissue procurement is not considered a bona fide service fee for the purposes of calculating the manufacturer's ASP since this is an integral part of the manufacturing process for autologous cell-based immunotherapy or gene therapy and should be included in the price of the product.

The following is a summary of the comments we received and our responses.

Comment: Several commenters requested additional details on documentation expectation for classifying payments for preparatory procedures as BFSFs for autologous cell-based immunotherapy or gene therapy.

Response: General BSFS documentation standards are addressed in section III.A.2.c. of this final rule. The policy in this section pertains only to the ASP reporting classification of manufacturer-paid preparatory procedures for autologous cell-based immunotherapy and gene therapy manufacturing and does not establish new submission requirements.

Comment: Many commenters did not agree with CMS' proposal to treat preparatory procedures—such as cell collection and local processing—as not BFSFs and to require their inclusion in the calculation of ASP. Commenters stated that payments for these procedures meet the regulatory BFSF criteria and that treating them as price concessions would artificially lower ASP and reimbursement, create operational burdens, and limit patient access. Some commenters requested CMS to address potential interactions between ASP and other pricing metrics. Commenters also stated that, for many beneficiaries, cell collection occurs at a different facility and by a different provider than the entity that ultimately administers and bills for the product.

Commenters further stated that CMS lacks explicit statutory authority to redefine ASP inputs in this manner because section 1847A of the Act ties ASP to sales to purchasers, not payments to non-purchasing service providers, and the Congress has not directed manufacturers to add specific manufacturing costs into ASP. Some commenters recommended that CMS delay implementation by 12 to 24 months, requested clarification that payments to non-purchasing third parties (for example, the American Red Cross) should not affect ASP calculations, and suggested for clearer guardrails for manufacturer-provider arrangements if manufacturers pay for cell collection or processing.

<u>Response</u>: We are persuaded by the commenters that when a manufacturer pays for a preparatory procedure, it could be classified as a bona fide service. Therefore, after consideration of public comments, we are not finalizing our proposal that such payments cannot be classified as BFSFs. Likewise, we are not finalizing the proposal to require inclusion in ASP, beginning January 1, 2026, of manufacturer-paid preparatory procedures for tissue procurement (including "cell collection") required for manufacturing an autologous cell-based immunotherapy or gene therapy product. Instead, we agree that manufacturer

payments for preparatory procedures—such as cell collection and local processing—may meet the four-part regulatory criteria for BFSFs under § 414.802 when they are itemized, represent FMV, are performed on behalf of the manufacturer, and are not passed through to a purchaser. These payments compensate for services integral to the manufacturing process and are not discounts or rebates that reduce the cost to the purchaser. When these criteria are satisfied, such payments are excluded from price concessions under § 414.804(a)(2)(ii); because ASP is calculated net of price concessions under section 1847A(c)(3) of the Act, these amounts are not deducted from ASP. These clarifications apply regardless of whether collection and infusion occur at the same or different facilities.

We believe this interpretation is most consistent with the statutory framework for ASP and the regulatory definition at § 414.802, and it avoids unintended downward pressure on ASP-based reimbursement that could impede beneficiary access. Because manufacturers already maintain documentation relevant to BFSF analyses, this clarification aligns ASP reporting with existing requirements and does not impose new burden. We reiterate that payments properly classified as BFSFs are not price concessions in ASP calculations, and manufacturers must continue to maintain documentation supporting their BFSF determinations and reasonable assumptions.

For payments made to non-purchasing third parties, payments that meet the BFSF criteria are excluded from ASP. More broadly, ASP represents the manufacturer's sales to all purchasers; therefore, payments to entities that do not purchase the product are not price concessions to a purchaser and, when properly classified as BFSFs, do not affect ASP.

This policy addresses only how manufacturer-paid amounts are reflected in ASP; it does not require hospitals or physicians to enter financial arrangements with manufacturers or dictate commercial terms. By not mandating such arrangements, we provide interested parties flexibility to structure relationships consistent with operational needs and applicable law, supporting site-specific decisions and reducing administrative burden. Except for the ASP reporting clarification described in this section, this final rule does not change any statutory or regulatory price-reporting definitions or methodologies, including AMP and best price.

d. Summary

In summary, we proposed that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself and that, beginning January 1, 2026, any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that were paid for by the manufacturer be included in the calculation of the manufacturer's ASP.

After consideration of public comments, we are finalizing, as proposed, continuation of the existing bundled payment policy for CAR T-cell therapies and extending that policy to autologous cell-based immunotherapy and gene therapy, such that preparatory procedures for patient-specific cell or tissue procurement required for manufacturing are included in the payment for the product itself. However, we are not finalizing the proposal to prevent these payments from qualifying as BFSFs or to require their inclusion in ASP beginning January 1, 2026. Instead, we conclude that such payments may be treated as BFSFs when the four-part test at § 414.802 is satisfied and therefore excluded from ASP, consistent with section 1847A(c)(3) of the Act and § 414.804(a)(2)(ii). This final rule maintains cross-setting alignment under the OPPS and PFS—where Medicare does not pay separately for each step used to manufacture a drug or biological but does pay separately for the administration service—and ensures that ASP reporting remains consistent with statutory and regulatory requirements.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background on RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405 subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse that is furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount per visit. As of April 1, 2021, all RHCs are subject to statutory upper payment limits determined in accordance with section 1833(f) of the Act, as amended by section 130 of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260).

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111-148)), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care

to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were initially designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. These nearly all-inclusive rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket reduced by a productivity adjustment. For CY 2025, we rebased and revised the 2017-based FQHC market basket to reflect a 2022 base year (89 FR 98023 through 98032).

2. Payment for Care Coordination Services

a. Background

In the last several years of rulemaking, we have expanded the scope of care coordination services (formerly referred to as care management services) that are billable using HCPCS code G0511. More recently, in the CY 2025 PFS final rule, we unbundled the individual HCPCS codes that make up G0511 (89 FR 97999 through 98000). We have also been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result, established codes and separate payment to independently recognize and pay for these important services. As stated in the CY 2016 PFS Final Rule (80 FR 71080 through 71088), the care coordination included in services, such as office visits, does not always adequately describe the non-face-to-face care management work involved in primary care and similar care relationships. We noted that payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

Over the last decade, we have updated RHC and FQHC payment policies as appropriate. We remain committed to improving how Medicare payment recognizes the resources involved in furnishing covered services. These services encompass aspects of advanced primary care furnished by

interprofessional care teams and typically concentrate on the delivery of appropriate preventive care to patients and the management of individuals' chronic conditions as they progress over time. As a result, we reaffirmed our support of primary care and recognized care management as one of the critical components of primary care by implementing significant changes aimed at better capturing the resources required for care management services, including chronic care management (CCM), principal care management (PCM), general behavior health integration (BHI), chronic pain management (CPM), transitional care management (TCM), remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), community health integration (CHI), principal illness navigation (PIN), PIN-peer support services and Advanced Primary Care Management (APCM). For RHCs and FQHCs, we established payment for these suites of care coordination services outside of the RHC AIR and FQHC PPS. That is, payment is made in addition to the otherwise billable visit.

In the CY 2025 PFS final rule (89 FR 97870 through 97874), we discussed how we established coding and payment under the PFS for a newly defined set of APCM services described and defined by three new HCPCS G-codes. This new coding reflects the recognized effectiveness and growing adoption of the advanced primary care approach to care. It also encompasses a broader range of services and simplifies the billing and documentation requirements, as compared to existing care management codes. The coding for APCM incorporates elements of several existing care management services into a bundle that we have already considered to be care coordination services paid separately to RHCs and FQHCs using HCPCS code G0511 (for example, CCM and PCM). In addition, the coding for APCM incorporates elements of communication technology-based services (CTBS) into a bundle that we have already considered to be virtual communications paid separately to RHCs and FQHCs using HCPCS code G0071. Therefore, to allow RHCs and FQHCs the ability to simplify the billing and documentation requirements associated with furnishing APCM services we finalized in the CY 2025 PFS final rule to allow RHCs and FQHCs to bill for these services and receive separate payment.

Further, the APCM code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner

(NPP) is used to meet time thresholds for billing. In the CY 2025 final rule, we adopted the three new APCM codes G0556, G0557, and G0558 as being payable in addition to the otherwise billable visit.

RHCs and FQHCs are required to use the more specific coding, that is, the three HCPCS G-codes listed above when furnishing APCM. These services are paid in addition to the otherwise billable visit under the RHC AIR methodology or FQHC PPS because we believe that they are similar to the other care coordination services, such as, CCM, PCM, and RPM. That is, APCM involves non-face to-face care coordination of which the costs associated with these services are not captured in the RHC AIR or FQHC PPS rate. Similarly to the care coordination services, payment for APCM is based on the PFS national non-facility rate. It is important to note that if RHCs and FQHCs furnish APCM services, the HCPCS codes for APCM are per calendar month bundles. Consequently, if the RHC or FQHC furnishes APCM then they would not bill for certain other individual care coordination services. For further discussion on duplicative services and concurrent billing restrictions regarding APCM policies, please refer to the CY 2025 PFS final rule (89 FR 97710).

b. Integrating Behavioral Health into Advanced Primary Care Management (APCM)

In the CY 2018 PFS final rule, we established requirements and separate payment for general Behavioral Health Integration (BHI) and Psychiatric Collaborative Care Model (CoCM) services furnished in RHCs and FQHCs (82 FR 53169 through 53180). General BHI and Psychiatric CoCM services are based on a model of behavioral health integration that enhances usual primary care by adding two key services to the primary care team: care management support for patients receiving behavioral health treatment and regular psychiatric inter-specialty consultation. In the CY 2018 PFS final rule, we also initiated the use of HCPCS codes G0511 and G0512 to pay for general care coordination services and CoCM services, respectively.

In the CY 2026 PFS proposed rule (90 FR 32549), we discussed how we recognize that patients with chronic health conditions are "more likely to have related behavioral health concerns and find it easier to improve chronic conditions when these concerns are also addressed."[154] Integrating behavioral health with primary care has been shown to improve outcomes like reduced depression severity, and

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[154] *https://integrationacademy.ahrq.gov/about/integrated-behavioral-health#:~:text=Integrated%20behavioral%20health%20offers%20many,these%20concerns%20are%20also%20addressed.*

enhancing patient's experience of care. [155] We further explained that in response to comments received for CY 2025 rulemaking, for services paid under the PFS, we proposed to create optional add-on codes for APCM services that would facilitate providing complementary BHI services. Section II.G.1. of this final rule provides more detail on the final policies under the PFS.

We also discussed how we adopted the coding for the defined set of APCM services described and defined by HCPCS codes G0556, G0557, and G0558 to allow RHCs and FQHCs the ability to simplify the billing and documentation requirements associated with furnishing APCM services. In addition, and similarly to the discussion in section II.G of this final rule, since RHCs and FQHCs that fulfill the requirements to bill for APCM services must comply with requirements that ensure the integrity of the services provided, we believe that these settings should also be able to provide BHI and CoCM with simpler billing and documentation requirements. Therefore, for CY 2026, in alignment with the PFS and goals associated with APCM services, we proposed to adopt the add-on codes for APCM that would facilitate billing for BHI and CoCM services when RHCs and FQHCs provide advanced primary care. As we stated, we believe allowing for the use of these add-on codes would encourage RHCs and FQHCs to provide complementary BHI services, thereby improving access to BHI and CoCM for primary care patients in the RHC and FQHC settings. For further discussion regarding the optional add-on codes, please see section II.G.2 of this final rule.

We further discussed that in the CY 2025 PFS final rule (89 FR 98010), commenters suggested that we consider unbundling HCPCS code G0512, similarly to what we did with HCPCS code G0511. That is, unbundle the services that comprise HCPCS code G0512 and permit billing of HCPCS codes 99492, 99493, and 99494. Commenters explained that allowing RHCs and FQHCs to report the dedicated CPT codes would support and encourage the adoption of CoCM in these settings. In addition, we explained that since we proposed using add-on codes for APCM services to facilitate payment of BHI and CoCM services when they are furnished by RHCs and FQHCs providing advanced primary care services, we would also need to unbundle HCPCS code G0512 to effectuate that policy. We stated that RHCs and FQHCs that are furnishing BHI and CoCM as advanced primary care services would not be able to bill

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[155] Balasubramanian, Bijal, Deborah Cohen, Katelyn Jetelina, Miriam Dickinson, Melinda Davis, Rose Gunn, Kris Gowen, Frank DeGruy 3rd, Benjamin Miller, Larry Green. "Outcomes of Integrated Behavioral Health with Primary Care." J Am Board Fam Med. 2017 Mar-Apr;30(2):130-139.doi: 10.3122/jabfm.2017.02.160234.

for certain other individual CPT codes, such as, 99492, 99493, and 99484.

Therefore, we proposed to require RHCs and FQHCs to report the individual codes that make up the CoCM HCPCS code, G0512 beginning January 1, 2026. Similar to what was finalized in the CY 2025 PFS final rule (89 FR 98000 through 98010) for the general care management HCPCS code G0511, HCPCS code G0512 would no longer be payable when billed by RHCs and FQHCs; instead, RHCs and FQHCs would be required to bill the individual CPT and HCPCS codes that make up HCPCS G0512. The current list of base codes and add-on codes that make up G0512 are listed in Table B-BA1, titled "Psychiatric Collaborative Care Model HCPCS Codes and Descriptors." Payment for these services would be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We proposed to revise § 405.2464(c) to reflect our proposal on payment of CoCM services for RHCs and FQHCs.

TABLE B-BA1: PSYCHIATRIC COLLABORATIVE CARE MODEL HCPCS CODES AND DESCRIPTORS

HCPCS Code	Short Descriptors	Long Descriptors
99492	1st psych collab care mgmt.; CoCM First Month, 70 minutes per calendar month	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and that the treating physician or other qualified health care professional directs, with the following required elements: ● Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional. ● Initial assessment of the patient, including administering validated rating scales, with the development of an individualized treatment plan ● Review by the psychiatric consultant with modifications of the plan, if recommended. ● Entering patient in a registry and tracking patient follow-up and progress using the registry, with proper documentation, and participation in weekly caseload consultation with the psychiatric consultant. ● Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.
99493	Sbsq psyc collab care management; CoCM Subsequent Months, 60 minutes per calendar month	Follow up psychiatric collaborative care management, first 60 minutes in a following month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care

HCPCS Code	Short Descriptors	Long Descriptors
		professional, with the following required elements: ● Tracking patient follow-up and progress using the registry, with proper documentation ● Participation in weekly caseload consultation with the psychiatric consultant. ● Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers. ● Other review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations supplied by the psychiatric consultant. ● Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies. ● Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms, other treatment goals and prepare for discharge from active treatment.
99494	1st/subesq psyc collab care; Add-on CoCM (any month), each additional 30 minutes per calendar month.	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and that the treating physician or other qualified health care professional directs (list separately from the code for the primary procedure).
G2214	Init/sub psych care m 1st 30; Initial or subsequent psychiatric collaborative care management, 30 minutes of behavioral health care manager time per calendar month.	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional: ● Tracking patient follow-up and progress using the registry, with proper documentation; participation in weekly caseload consultation with the psychiatric consultant. ● Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers. ● Other review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations supplied by the psychiatric consultant. ● Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies. ● Monitoring of patient outcomes using validated rating scales. ● Relapse prevention planning with patients as they achieve remission of symptoms, or other

HCPCS Code	Short Descriptors	Long Descriptors
		treatment goals and prepare for discharge from active treatment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposal to adopt the optional add-on codes for APCM that would facilitate billing for BHI and CoCM services when RHCs and FQHCs provide advanced primary care management. Commenters agreed that adoption of the optional add-on codes would facilitate billing for BHI and CoCM services provided by RHCs and FQHCs, incentivize RHCs and FQHCs to adopt integrated care services, strengthen integrated behavioral health in primary care, minimize documentation requirements, increase access to critical behavioral health services and provide flexibility for RHCs when choosing the most appropriate care management option for their patients and clinic's capacity.

A few commenters expressed their support for these proposals but had concerns. Some commenters were concerned about the RHC uptake of the new codes. These commenters requested CMS to provide additional support via resources, education, guidance and training on the billing codes to effectuate the use of these services and to minimize billing and compliance barriers. Other commenters requested CMS provide clarity around payment, duplication and assignment, and requested that CMS provide a table in the final rule that would summarize when APCM may be billed with CCM, PCM, RPM, RTM, and CTBS across settings. These commenters stated that RHCs are small healthcare providers with limited resources and capacity to provide new, innovative services.

A few commenters requested clarity on how the BHI and CoCM services will be categorized for RHCs with regard to the 50 percent threshold. They explained that RHCs are currently surveyed based on the total number of hours spent providing primary care versus behavioral health care and can be cited if their hours spent providing the latter exceed 50 percent. These commenters expressed concern that counting BHI and CoCM as behavioral health services would discourage RHCs from providing these services and requested that CMS count BHI and CoCM as primary care, given that they are add-on codes for APCM, and that CMS provide sub-regulatory guidance to that effect.

A few commenters had concerns about cost-sharing and indicated that beneficiaries receiving

care at RHCs and FQHCs are often financially unstable and the monthly cost for some of these recurring services may discourage them from seeking them out. These commenters supported the proposal to allow for billing of BHI and CoCM codes in conjunction with APCM codes but urged CMS to remove cost-sharing from all APCM codes. Another commenter expressed concerns about cost-sharing requirements stating that for many Part B beneficiaries, these costs may discourage patients from accessing behavioral health services, generally. Lastly, these commenters recommended that CMS categorize components of APCM and behavioral health services as preventive services which they believe would eliminate the cost-sharing barrier for underserved RHC and FQHC patients.

A commenter urged CMS to delay the implementation of the proposal to adopt the add-on codes for APCM that would facilitate billing for BHI and CoCM services for RHCs and FQHCs, stating that creating optional add-on codes could cause the conversion factor to decrease and reduce payment. The commenter urged CMS to delay implementation and requested that CMS engage interested parties in conversation on potential implications to budget neutrality and the downstream impacts on the PFS conversion factor.

A few commenters stated that they did not agree with the proposal until the current APCM codes have been widely implemented and researched. Other commenters recommended CMS not create optional add-on codes for behavioral health services with APCM stating that FQHC's have varying levels of integration, which include coordination and co-location of primary care and behavioral health facilities and services. These commenters stated that add-on codes for APCM may be difficult for FQHCs to implement and would not encourage increased utilization. They requested that CMS ensure adequate payment for BHI and CoCM services, if we move forward with finalizing this proposal.

Response: We thank commenters for their supportive comments. Regarding commenter concerns for additional support via guidance on new billing codes to effectuate the use of these services, we plan to issue sub-regulatory guidance and other educational resources that will help RHCs and FQHCs minimize billing and compliance barriers by providing clarity around payment, assignment and duplication of codes.

Regarding the comments about the categorization of BHI and CoCM services and the total hours spent providing primary care versus behavioral health services, we note that in the CY 2025 PFS final

rule we discuss finalized policy around primary care and behavioral health services. In the discussion we explain that CMS will no longer determine or enforce the standard of RHCs ''being primarily engaged in furnishing primary care services.' This policy was implemented via the sub-regulatory guidance contained in the State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs). In the CY 2025 PFS final rule, we stated that we believe this change would provide RHCs with additional flexibility to provide outpatient specialty services on-site or hire additional providers with specialized expertise to meet the needs of their community (89 FR 98518 and 98519).

Regarding commenters' requests for waiving coinsurance costs, we are aware that the copayment and/or deductible in RHCs and the copayment in FQHCs can be a barrier for some beneficiaries, but we do not have the statutory authority to waive these charges. Because these services are typically furnished non-face-to-face, and therefore, are not visible to the patient, it is important that adequate information is given to patients during the consent process on cost-sharing responsibilities and the benefits of care management services. RHCs and FQHCs should also provide information on the availability of assistance to qualified patients in meeting their cost-sharing obligations, or any other programs to provide financial assistance, if applicable. Regarding the comment about preventive services, as we discuss in section II.G.4 of this final rule, we solicited comments on how CMS could consider including preventive services within the APCM bundles. We thank the commenter for this feedback, and we may take the comments into consideration for possible future rulemaking.

About commenters' concerns on the impact this proposal may have on budget neutrality and downstream impacts on the PFS conversion factor, we note physicians and practitioners are paid under the PFS. Section 1848 of the Act is the section of the statute that governs payment under the PFS and, the provisions related to budget neutrality and the conversion factor (CF) are under the PFS in subsections (c) and (d) of this section. Payments to RHCs and FQHCs are not governed by section 1848 of the Act; instead, they are governed by sections 1833(f), 1833(a)(3) and 1834(o) (FQHC PPS), of the Act. Under these sections, generally, RHCs are paid under an all-inclusive rate (AIR) methodology and FQHCs are paid under the FQHC PPS for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). Both the RHC AIR and FQHC PPS rates were initially designed to reflect the cost of all services and supplies that an RHC or

FQHC furnished to a patient in a single day. Given this, neither payment structure is subject to budget neutrality under statute, and it is important to reiterate that our proposal was to pay for these services as add-on services to APCM which is paid separately from the RHC AIR and FQHC PPS and is based on the PFS national non-facility payment rate.

After consideration of public comments, we are finalizing our proposal to adopt the add-on codes for APCM that would facilitate billing for BHI and CoCM services when RHCs and FQHCs provide advanced primary care, as proposed. For CY 2026, RHCs and FQHCs furnishing APCM services may report HCPCS code G0568, G0569, or G0570 when they integrate behavioral health services with these services.

Comment: A commenter stated that they appreciated CMS's proposal to allow FQHCs and RHCs to bill APCM codes along with mental health and substance use disorder (SUD) services. They noted that these types of facilities have different models for and types of integration, and as such, they recommended CMS work with interested parties from these facilities before finalizing coding or payment policies to ensure that any new policies are not inadvertently limiting access to these types of services or creating additional burdens for FQHCs and RHCs. The commenter also encouraged CMS to revisit and expand the codes that can be used to meet the definition of a qualifying behavioral health visit.

Response: We appreciate the commenter's feedback regarding the billing of APCM codes by FQHCs and RHCs in conjunction with mental health and SUD services. CMS is committed to ensuring that policies do not inadvertently limit access to essential healthcare services or impose undue burdens on providers and suppliers. We agree with commenters that there are FQHCs and RHCs that have established models of care planning and integration of behavioral health services. We believe that the policies we are finalizing for CY 2026 allow these settings flexibility to furnish APCM with BHI or CoCM or they can continue to furnish these services as they currently do. As we discuss in the CY 2025 PFS final rule (89 FR 97999 – 98010), for care coordination services, FQHCs and RHCs must bill the individual CPT or HCPCS codes that describes the service they furnish, which includes BHI services. Payment for these services is based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. With regard to HCPCS code G0512 (RHC/FQHC psychiatric

CoCM, 70 min+), please see below for our final policy to unbundle this code.

Comment: A commenter supported CMS' proposal to recognize Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs) as Medicare practitioners and to make their services mandatory FQHC benefits. The commenter stated that this aligns with New York State Medicaid policy and will significantly expand the behavioral health workforce available to Medicare patients, particularly in rural and underserved communities.

Response: We appreciate the commenters' support of MHCs and MFTs being recognized as Medicare practitioners in FQHCs. We remind commenters, in the CY 2024 PFS final rule (88 FR 79067 – 79060), we discuss how section 4121(b) of CAA, 2023 amended section 1861(aa)(1)(B) of the Act by extending the scope of RHC services to include those furnished by MFTs and MHCs as eligible for payment, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. Therefore, effective January 1, 2024, RHC and FQHCs are paid under the RHC AIR and FQHC PPS, respectively, when MFTs and MHCs furnish RHC and FQHC services defined in §§ 405.2411 and 405.2446.

We also received several comments on our proposal to require RHCs and FQHCs to unbundle HCPCS codes G0512 and bill the respective individual codes that make up G0512, beginning January 1, 2026. We did not receive comments on our proposal to revise § 405.2464(c) to reflect changes for payment of CoCM services for RHCs and FQHCs. The following is a summary of the comments we received and our responses.

Comment: Many commenters largely supported our proposal to unbundle HCPCS code G0512 and bill for the respective individual codes that make up G0512. Commenters stated that this change would eliminate barriers to providing CoCM services in the RHC and FQHC settings. Commenters stated that this change would enhance transparency by giving clinics and policymakers better insight into utilization patterns across different practice types, geographic regions, and patient populations. Other commenters stated that this change will better capture clinical complexity, strengthen financial sustainability for safety-net providers and expand access to evidence-based collaborative care in underserved communities. Some commenters stated that this change will allow for greater streamlining of work for FQHCs, RHCs, and CMS. Other commenters stated that this proposal would support quality

improvement initiatives and outcome measurement efforts.

A commenter supported the proposal stating that this change will likely improve payment accuracy and more accurately reflect the diverse range of services furnished in these settings and aligning payment more closely with the actual care delivered; however, the commenter requested CMS to clearly state which clinical staff may perform these services under physician direction and explore opportunities to enhance transparency, service attribution and outcomes tracking by rendering provider or clinical staff, while minimizing additional administrative burden for billing the individual codes for CoCM rather than relying on the bundled HCPCS G0512 code.

A few commenters recommended that CMS provide robust guidance, education and technical assistance to avoid undue administrative burden and potential unbundling billing confusion. Other commenters urged CMS to prioritize timely updates and resources to RHCs to ensure full participation in chronic care management programs. Some commenters discussed the issues that they experienced with unbundling HCPCS code G0511 which was finalized in the CY 2025 PFS final rule and noted how this policy's implementation has been extended twice (that is, July 1, 2025 and then September 1, 2025). The commenters requested that CMS provide technical support with the current unbundling process and apply lessons learned to the proposal for unbundling HCPCS code G0512.

Response: We thank commenters for their supportive comments. With regard to which clinical staff may perform psychiatric CoCM, these services are team-based collaborative approaches to care that focus on integrative treatment of patients with primary care and mental or behavioral health conditions. Psychiatric CoCM is a specific model of care provided by a primary care team consisting of a primary care provider and a health care manager who works in collaboration with a psychiatric consultant. CPs, CSWs, MFTs, and MHCs are RHC and FQHC practitioners and furnish medically necessary, face-to-face services that may be stand-alone billable visits in RHCs and FQHCs. They can also serve as the behavioral health care manager for psychiatric CoCM services. In order to facilitate the integration and coordination of the patient's primary care and mental or behavioral health conditions, these care management services are furnished under the direction of the RHC or FQHC primary care practitioner. Only services furnished by an RHC or FQHC practitioner or auxiliary personnel that are within the scope of service elements can be counted toward the time that is required to bill for psychiatric CoCM services

and does not include administrative activities such as transcription or translation services. More information regarding psychiatric CoCM services furnished in RHCs and FQHCs is available in Pub. 100-02 Medicare Benefit Policy Manual, Chapter 13, section 230.4.

For the commenters who expressed a need for robust guidance on billing and the unbundling HCPCS code G0512, we plan to issue sub- regulatory guidance via updating multiple resources including the RHC and FQHC Medicare Benefit Policy Manual, MLN publications and the RHC and FQHC web pages to help RHCs/FQHCs understand how to navigate the unbundling process. Regarding commenters who noted the implementation issues of unbundling HCPCS code G0511, we acknowledge that there were Medicare claim processing issues that presented billing challenges for RHCs and FQHCs. We have since resolved those issues and intend to use lessons learned from those issues and apply to the unbundling process for HCPCS G0512.

After consideration of public comments, we are finalizing our proposal to require RHCs and FQHCs to report the individual codes that make up the CoCM HCPCS code, G0512 beginning January 1, 2026. That is, HCPCS code G0512 will no longer be payable when billed by RHCs and FQHCs; instead, RHCs and FQHCs will be required to bill the individual CPT and HCPCS codes that make up HCPCS G0512. The current list of base codes and add-on codes that make up G0512 are listed in Table B-BA1, titled "Psychiatric Collaborative Care Model HCPCS Codes and Descriptors." Payment for these services will be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We are also finalizing the revisions to § 405.2464(c) to reflect the change for payment of CoCM services for RHCs and FQHCs.

We note, in Table 34 of the CY 2026 PFS proposed rule (90 FR 32550 – 32551) we included two codes in the current list of base codes and add-on codes that make up HCPCS code G0512 that we haven't recognized for payment for RHCs and FQHCs previously. Specifically, CPT code 99494 (1st/subesq psyc collab care; Add-on CoCM (any month), each additional 30 minutes per calendar month) and HCPCS code G2214 (Init/sub psych care m 1st 30; Initial or subsequent psychiatric collaborative care management, 30 minutes of behavioral health care manager time per calendar month).

As discussed in the CY 2025 PFS final rule (89 FR 98000 – 98010), RHCs and FQHCs are

required to bill using the individual codes that made up G0511 to receive separate payment for care coordination services. As part of the payment policy, we stated that RHCs and FQHCs can bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter. For this final rule, we clarify and to be consistent with how we paid for the services that made up HCPCS code G0511, beginning January 1, 2026, RHCs and FQHCs can bill CPT code 99494.

In the CY 2021 PFS final rule (85 FR 84547 – 84548), for practitioners billing under the PFS, we established a G-code to describe 30 minutes of behavioral health care manager time. That is, HCPCS code G2214 (Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional) was established to capture shorter increments of time spent. For example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. At the time of the CY 2021 PFS rulemaking we did not address the applicability of G2214 for RHC and FQHC purposes. For this final rule, we clarify and to be consistent with how we pay for CoCM, beginning January 1, 2026, RHCs and FQHCs can bill CPT code G2214.

Comment: A commenter urged CMS to implement a policy to allow FQHCs and RHCs to bill for Community Health Integration (CHI) and Principal Illness Navigation (PIN) services, using the same set of HCPCS codes available to traditional healthcare providers. The commenter further stated that FQHCs and RHCs should be afforded the opportunity to bill for CHI and PIN services with no cap or limit on the volume of services rendered to a beneficiary per calendar month.

Response: We refer the commenter to the CY 2025 PFS final rule (89 FR 97999 – 98010) where we discussed and finalized the policy to bill individual HCPCS code for CHI and PIN services.

Comment: We received comments that were out of scope for these proposals. Several commenters encouraged CMS to revise the definition of a behavioral health visit for RHCs and FQHCs to expand the types of HCPCS codes that can be billed as a qualifying visit. Another commenter would like CMS to allow Opioid Treatment Programs that have formal care coordination agreements with RHCs and FQHCs, to bill the CoCM add-on codes for team-based care, including medications for opioid use disorder.

Response: We thank the commenters for their feedback; however, these comments are outside the

scope of these proposals. We may take these comments into consideration for further evaluation.

c. Payment for Communication Technology-Based Services (CTBS) and Remote Evaluation Services – HCPCS Code G0071

In the CY 2019 PFS final rule (83 FR 59683 through 59688), we established requirements and separate payment for certain CTBS and remote evaluation services in RHCs and FQHCs. Effective January 1, 2019, RHCs and FQHCs are paid for HCPCS code G0071 (Virtual Communication Services), when HCPCS code G0071 is on an RHC or FQHC claim, either alone or with other payable services, and at least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who has had an RHC or FQHC billable visit within the previous year, and the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment. At that time, HCPCS code G0071 comprised individual HCPCS codes G2012 (CTBS) and G2010 (remote evaluation services). For respective CTBS code descriptors, please refer to Table B-BA2. The payment rate for HCPCS G0071 was set at the average of the PFS national non-facility payment rates for HCPCS code G2012 and HCPCS code G2010 for remote evaluation services.

(1) Updates to CTBS and Remote Evaluation Services Under the PFS

In the CY 2021 PFS final rule (85 FR 84532 through 84533), for practitioners billing under the PFS, we discuss additional policies as they relate to CTBS services. One of which was the establishment of HCPCS code G2250, which allows billing of CTBS by certain non-physician practitioners (NPPs), consistent with the scope of these practitioners' benefit categories, who cannot independently bill for evaluation and management (E/M) services.

In the CY 2026 PFS proposed rule (90 FR 32551 – 32553), we noted that at the time of the CY 2021 PFS rulemaking we did not address the applicability of G2250 for RHC and FQHC purposes. However, we acknowledged that the code descriptor for HCPCS code G2250 mirrors that of the existing HCPCS code G2010 in that both codes describe the remote assessment of recorded video and/or images submitted by an established patient (for example, store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the

previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment. We explained that since HCPCS code G2250 describes remote evaluation services similarly to HCPCS code G2010 and certain non-physician practitioners are recognized as RHC and FQHC practitioners, we proposed to consider HCPCS code G2250 as billable for separate payment when this service is furnished in an RHC or FQHC.

We also discussed that in the CY 2025 PFS final rule (89 FR 97791 through 97794), for practitioners billing under the PFS, the CPT Editorial Panel established new CPT code 98016 describing a brief virtual check-in encounter that is intended to evaluate the need for a more extensive visit (that is, a visit described by one of the office/ outpatient E/M codes). We stated that the code descriptor for CPT code 98016 mirrored the existing HCPCS code G2012, which is described as a brief communication technology-based service, for example, virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5 to 10 minutes of medical discussion). We further stated that given the similarity between CPT code 98016 and HCPCS code G2012, we finalized the replacement of HCPCS code G2012 with CPT 98016. That is, HCPCS code G2012 was terminated effective December 31, 2024.

In the CY 2026 PFS proposed rule (90 FR 32552), we stated that we inadvertently did not discuss the applicability of this code termination to RHCs and FQHCs; however, given our alignment with the PFS, beginning January 1, 2025, for HCPCS code G0071, CPT code 98016 was used for purposes of computing the payment rate.

(2) CTBS and Remote Evaluation Services

In the CY 2026 PFS proposed rule (90 FR 32552 – 32554) we discussed the connection between APCM, CTBS and remote evaluation services. APCM includes elements of CTBS and remote evaluation services, however in the CY 2025 PFS final rule, we did not address how there are potential duplicative services with APCM and these services for RHCs and FQHCs (89 FR 98010 through 98012). We stated that similarly with unbundling of G0512, we believe that we would also need to unbundle HCPCS code G0071 to better effectuate the payment policy for APCM. We explained that RHCs and FQHCs that are

furnishing CTBS or remote evaluation services as advanced primary care services would not be able to bill for certain other individual CPT codes, such as, G2010, G2250, and 98016. Therefore, we proposed to require RHCs and FQHCs to report the individual codes that make up HCPCS code G0071 beginning January 1, 2026. Payment for these services would be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We proposed revising 405.2464(e) to reflect our proposal for payment of CTBS and remote evaluation services for RHCs and FQHCs.

TABLE B-BA2: CODE DESCRIPTORS FOR COMMUNICATION TECHNOLOGY-BASED SERVICES AND REMOTE EVALUATION SERVICES

HCPCS Code	Short Descriptors	Long Descriptors
G0071	Communication Services by RHC/FQHC 5 minutes	Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between an rural health clinic (RHC) or Federally qualified health center (FQHC) practitioner and RHC or FQHC patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an RHC or FQHC practitioner, occurring in lieu of an office visit; RHC or FQHC only.

HCPCS Code	Short Descriptors	Long Descriptors
G2010	Remote image submit by patient	Remote evaluation of recorded video and/or images submitted by an established patient (for example, store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment).
G2012	Discontinued - Brief check in by MD/QHP	Brief communication technology-based service, for example, virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5 to 10 minutes of medical discussion.
G2250	Remote image submitted by patient, non-E/M	Remote assessment of recorded video and/or images submitted by an established patient (for example, store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.
98016	Brief communication technology-based service	Established patient brief communication technology-based service with 5 to 10 minutes of medical discussion.

We received several comments on our proposals to require RHCs and FQHCs to report the individual codes that make up the CTBS and Remote Evaluation Services HCPCS code G0017 beginning January 1, 2026. We did not receive comments on our revisions to § 405.2464(e) to reflect changes for payment of CTBS and remote evaluation services for RHCs and FQHCs. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of our proposal to unbundle G0071 and require RHCs and FQHCs to report and bill for the individual codes (HCPCS G2210, G2250, and CPT 98016) that make up G0071. Some of the commenters stated that unbundling G0017 would provide a streamlined

framework for adding other care coordination services and improve transparency. Commenters thanked CMS for their efforts to ensure that RHCs and FQHCs are appropriately paid. Some commenters stated that allowing RHCs and FQHCs to bill individual codes would create payment parity while other commenters believe that the proposal would improve care access.

A few commenters expressed their support for unbundling G0071 but had some concerns. Commenters recommended that CMS provide robust guidance and resources, apply lessons learned with unbundling HCPCS G0511 and provide technical assistance to help RHCs and FQHCs implement the change, mitigate issues, and avoid service disruption, undue burden and confusion. A commenter requested clear guidance on overlap with APCM months to know when standalone CTBS codes are ineligible due to APCM bundling. Another commenter recommended CMS delay the unbundling of G0071 to allow more time to engage interested parties and give consideration to primary care physicians already facing a complex array of coding options for care management. The commenter expressed concern that the unbundling of G0071 alongside the introduction of new time-based CPT codes under APCM risks adding further confusion, particularly for smaller practices and could exacerbate administrative burden, reduce reimbursement for providers, and create confusion. This commenter recommended that CMS finalize this update and invest in targeted education and technical assistance to support the adoption of G2250. A few commenters believed that there would be an increase in utilization and urged CMS to increase the payment rate for APCM bundling to better account for patient care costs and the loss of concurrent billing with G0071.

Response: We thank commenters for their supportive comments. Regarding commenters' requests for robust guidance, we will issue sub-regulatory guidance via updating multiple resources including the RHC and FQHC Medicare Benefit Policy Manual, MLN publications and the RHC and FQHC web pages to help RHCs and FQHCs understand how to navigate the unbundling process and mitigate potential implementation, billing and compliance issues that could accompany the unbundling of HCPCS G0071.

For those commenters who expressed concern about the loss of concurrent billing with G0071 and requested an increase in APCM payment rates, similar to our decision about the payment rate for HCPCS codes G0511 and our proposal for HCPCS code G0512 payment rate, HCPCS code G0071 will

be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes.

After consideration of the public comments, we are finalizing requiring RHCs and FQHCs to report the individual codes that make up HCPCS code G0071. That is, beginning January 1, 2026, RHCs and FQHCs furnishing these services must report HCPCS codes G2010, G2250, and CPT code 98016 to receive separate payment. Payment for these services will be based on the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We are finalizing revisions to § 405.2464(e) to reflect the changes for payment of CTBS and remote evaluation services for RHCs and FQHCs.

d. Aligning with the PFS for Care Coordination Services

(1) Background

Under the PFS, certain care management/coordination services are categorized as designated care management services and assigned general supervision for purposes of "incident to" billing. As we discuss in the CY 2017 PFS final rule (81 FR 80238), generally, we do not believe it is clinically necessary for the individuals on the team who provide these services other than the treating practitioner (namely, clinical staff) to have the treating practitioner immediately available to them at all times, as would be required under a higher level of supervision. We also discussed how the regulations under § 410.26(b), at that time, provided for an exception to assign general supervision to CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are generally non-face-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner (who is also the supervising practitioner) is not physically present; and the CPT codes comprise solely (or to a significant degree) non-face-to-face services provided by clinical staff (81 FR 80255).

For practitioners billing under the PFS, to better define general supervision and to assign general supervision not only to CCM services and the non-face-to-face portion of TCM services, but also to the then proposed codes, we amended §§ 410.26(a)(3) and 410.26(b). We amended § 410.26(a)(3) to better

describe general supervision in the context of these services and amended § 410.26(b) to assign general supervision to "designated care management services", stating that we will designate such services through notice and comment rulemaking (81 FR 80255 through 80256). We state at § 410.26(b)(5) that designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

Since CY 2017, when new care management/coordination services are proposed under the PFS, we also proposed to add the new codes, when applicable, to the list of designated care management services for which we allow general supervision. Each year, along with the proposed rule and the final rule, we have published the codes for designated care management services assigned general supervision as supporting documentation. For example, for the CY 2025 PFS final rule, the file is titled "CY 2025 Final Rule List of Designated Care Management Services."

(2) RHC and FQHC Care Coordination Services

In the CY 2026 PFS proposed rule (90 FR 32554 – 32555) we observed that over the last several years we have been increasing our focus on care coordination. We explained that these services have evolved to focus on preventing and managing chronic disease, improving a beneficiary's transition from the hospital to the community setting, or on integrative treatment of patients with behavioral health conditions. Care coordination services are typically non-face-to-face services that do not require the skill level of an RHC or FQHC practitioner. We noted our acknowledgement that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved and may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries.

We noted that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC (80 FR 71081). We explained that since this is the case, we have proposed payment policies for RHCs and FQHCs that complement the new services for care

coordination established under the PFS to align use of the RHC and FQHC resources for those services with a separate payment.

We noted that over the last decade, the number of new care coordination services established under the PFS has increased. As these services are proposed, we review and evaluate the new care coordination codes each year as established under the PFS to determine their applicability to RHCs and FQHCs. Our general process is to review the descriptor and policies under the PFS for each new HCPCS code to determine if the services are provided face-to-face with a practitioner or auxiliary personnel with a patient, or have some face-to-face component with a practitioner or auxiliary personnel or are strictly non-face-to-face; that is, the care coordination services are being performed behind the scenes and not in the presence of the patient. We stated that if the new care coordination service met the non-face-to-face criteria for RHCs and FQHCs, we would propose in the proposed rule adding it to the list of care coordination services that can be paid separately from a billable visit for RHCs and FQHCs. We noted that there is a detailed history on the payment for care coordination services available in the CY 2025 PFS final rule (89 FR 97998 through 98010).

We further explained that the increase in frequency of this complementary rulemaking has prompted us to consider operational efficiencies that we believe could result in more transparency and clarity in determining applicable care coordination services for RHCs and FQHCs. In the CY 2025 PFS final rule (89 FR 98012), we solicited comment on how we can improve the transparency regarding which HCPCS codes are considered care coordination services. We stated that our goal is to classify care coordination services established under the PFS that extend to RHCs and FQHCs. We also stated that we believe establishing a streamlined policy regarding which services are separately paid for RHCs and FQHCs versus which services are included as part of the visit creates transparency. We further stated that we believe establishing a policy where codes are communicated and updated through subregulatory guidance such as manuals, website pages, and change requests may be more efficient.

In the CY 2026 PFS proposed rule (90 FR 32555), we noted that only a few commenters responded to our request for information on how we can improve transparency and predictability regarding which HCPCS codes are considered care coordination services. These commenters agreed with a streamlined approach and that communicating these updates through sub-regulatory guidance would be

more transparent and efficient. Commenters stated that by distinguishing services that are separately payable from those services included in a visit, we would provide RHCs and FQHCs the clarity needed to accurately submit claims for Medicare reimbursement.

In response to the comment solicitation, we proposed adopting services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs. We stated that we believe this would improve transparency and efficiency for RHCs and FQHCs since these services and their designation as care management services go through notice and comment rulemaking. In addition, as discussed under §§ 405.2413 and 405.2415, we noted that service and supplies furnished incident to TCM and care coordination services can be furnished under general supervision.

In the CY 2026 PFS proposed rule (90 FR 32555), we discussed the proposed process but first reiterated what happens under the PFS to help explain the connection between that payment system to the proposed payment policy for RHCs and FQHCs. Under the PFS, when new care management/coordination services are proposed under the PFS, we also propose to add the new codes, when applicable, to the list of designated care management services for which we allow general supervision. Each year, along with the proposed rule and the final rule, we have published the codes for designated care management services assigned general supervision as supporting documentation. For example, for the CY 2025 PFS final rule, the file is titled "CY 2025 Final Rule List of Designated Care Management Services." We stated that under our proposal, services designated as care management services and added to the list of designated care management services would also be furnished in RHCs and FQHCs and paid separately as described in § 405.2464(c). Interested parties can look for opportunities to review and comment on new services in the respective sections of the PFS proposed and final rules. When services are finalized under the PFS, we proposed to update RHC and FQHC sub-regulatory guidance to reflect the new care coordination services. We stated that we expect to adopt any new care management services that are proposed and finalized in the CY 2027 PFS rule and displayed on the list of the designated care management services to be care coordination services for RHCs and FQHCs.

We then clarified how the payment for these services would be based and made. That is, any new

care coordination HCPCS codes will be paid separately from the RHC AIR methodology or FQHC PPS at the national non-facility PFS payment rate, either alone or with other payable visits. We noted that some of the current RHC and FQHC care coordination services are not listed on the current list of designated care management services, however, we confirmed the continuation of making separate payments for these RHC and FQHC care coordination services since they have been previously adopted through notice and comment rulemaking. These services include CCM, PCM, BHI, CPM, RPM, RTM, CHI, PIN and PIN-peer support services, and APCM.

We solicited comments on whether the proposed process which is to align with the care coordination services paid under the PFS as care management services is sustainable moving forward or is there a more effective approach for adopting new care coordination codes established under the PFS as care management codes that would improve transparency and efficiency for RHCs and FQHCs.

We received several public comments on our proposal to adopt services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs. The following is a summary of the comments we received and our responses.

Comment: Commenters were very supportive of the proposal and our proposed process. Commenters believe aligning with the PFS will allow familiarity with the same set of codes across settings of care, streamline documentation requirements, reduce provider stress and staff time, lower both administrative barriers and financial burdens for healthcare providers, ensure providers are adequately paid for these services, increase clarity, improve efficiency, and promote care coordination.

Response: We thank the commenters for their support of this proposal. We agree that adopting services that are established and paid under the PFS and designated as care management services as care coordination services that can be furnished in RHCs and FQHCs will address potential barriers for healthcare providers and promote transparency across settings of care.

We received a few comments on our comment solicitation on whether the proposed process is sustainable moving forward or if there is a more effective approach for adopting new care coordination codes.

Comment: A commenter suggested that any services which are partially paid for under the PFS

and partially paid for under the RHC AIR or FQHC PPS rate be considered care coordination and be paid under one payment system. The commenter believed that this structure would streamline work, and CMS would no longer have to include separate proposals for updates to coding and payments related to care coordination. Some commenters suggested CMS consider all care coordination services as health promotion services and stated that these services are not subject to copayments. Another commenter suggested we provide clear implementation guidance for RHC and FQHC practitioners. A commenter recommended that CMS conduct an evaluation to separately pay remote patient monitoring (RPM) and remote therapeutic monitoring (RTM) services from the RHC AIR and FQHC PPS to better support the scope and value of these services.

Response: We thank the commenters for their suggestions. We are unclear about what the commenter meant by partially paid services, but note that we are finalizing this proposal so that we do not have to make separate proposals for updates to coding and payments related to care coordination services in future rulemaking. We are also unclear about what another commenter meant by health promotion services, however we do not have the statutory authority to waive co-payments for care coordination services. We agree that it is important to communicate any changes made to the list of care coordination services and will update the list on an annual basis through sub-regulatory guidance to provide transparency and clarity for RHCs and FQHCs. We note that RPM and RTM services are currently paid separately from the RHC AIR and FQHC PPS as care coordination services.

After consideration of public comments, we are finalizing our proposal to adopt services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs . We believe that this alignment with designated care management services under the PFS promotes transparency across settings of care.

When new care management/coordination services are proposed under the PFS and are also proposed to be added to the list of designated care management services, RHC and FQHC interested parties should look for opportunities to review and comment on these new services in the respective sections of the PFS proposed and final rules. Under this process, services designated as care management services and added to the list of designated care management services would also be furnished in RHCs and FQHCs and paid separately as described in § 405.2464(c). When these services are finalized under

the PFS, we will update the list of care coordination services annually through sub-regulatory guidance to provide RHCs and FQHCs the clarity needed to accurately submit claims for Medicare payment.

We note, as discussed in section II.G. of this final rule, the optional add-on codes for APCM services are considered a ‘‘designated care management service’’ under § 410.26(b)(5) and, as such, can be provided by auxiliary personnel under the general supervision of the billing practitioner. Therefore, exemplifies the alignment with our final policy discussed in section III.B.2.b of this final rule.

3. Services Using Telecommunications Technology

a. Background

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116-136, March 27, 2020) directed the Secretary to establish payment for RHC and FQHC services that are provided as Medicare telehealth services by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID-19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by section 3704 of the CARES Act, required that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID-19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. We established payment rates for these services furnished by RHCs and FQHCs based on the average PFS payment amount for all Medicare telehealth services, weighted by volume in a Special Edition Medicare Learning Network Article (SE20016). We subsequently finalized a policy to extend use of this payment methodology for these services through CY2025.

Section 303 of the Consolidated Appropriations Acs (CAA), 2022, section 4113(c) of CAA, 2023, section 3207(c) of the American Relief Act, 2025, and section 2207(c) of the Full-Year Continuing Appropriations and Extensions Act, 2025 each subsequently extended these flexibilities. Most recently, section 2207(c) of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section

1834(m)(8) of the Act to continue payment for RHC and FQHC services as Medicare telehealth services through September 30, 2025.

In addition to the statutory and associated rulemaking changes noted previously, we established various flexibilities related to use of telecommunications technology through rulemaking; for example, in the CY 2022 PFS final rule with comment period (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in-person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner, and we revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder.

We also revised § 405.2469, to add a supplemental wraparound payment to be made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. We noted that these changes aligned with similar changes for Medicare telehealth services for behavioral health paid under the PFS. We also noted that this change would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

In addition, in the CY 2022 PFS final rule (86 FR 65210 and 65211), we revised the regulations at §§ 405.2463 and 405.2469 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated

with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record. In the CY 2025 PFS final rule, we announced that we would continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.

We stated in the CY 2026 PFS proposed rule (90 FR 32555-32556) that subsequent to the publication of the CY 2025 PFS final rule, section 2207(d) of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119-4, March 15, 2025) legislated the in-person visit requirement for mental health visits following September 30, 2025; therefore we are implementing conforming regulatory changes as discussed in section III.B.3.d. of this final rule.

As an additional regulatory flexibility, in the CY 2025 PFS final rule (89 FR 98013 through 98017), we extended our policy to deem the presence of the physician (or other practitioner) to include virtual presence for the purposes of direct supervision through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

b. Direct Supervision via Use of Two-way Audio/Video Communications Technology

Under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. See section II.D.2 of this final rule for the discussion regarding direct supervision for services provided using telecommunications technologies under the PFS.

In the CY 2024 PFS final rule (88 FR 79067), we explained that extending this definition of direct supervision for RHCs and FQHCs under our regulations at §§ 405.2413, 405.2415, 405.2448, and 405.2452 through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. In addition, we were concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2024, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID-19. We also believed that RHCs and FQHCs would need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Similar to services furnished in physician office setting, RHC and FQHC services and supplies furnished

incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care coordination services which may be furnished under general supervision. For CY 2024 we continued to define "immediate availability" as including real-time audio and visual interactive telecommunications through December 31, 2024, and solicited comment on whether we should consider extending the definition of "direct supervision" to permit virtual presence beyond December 31, 2024; specifically, we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have had in regard to this policy. In the CY 2025 final rule, (89 FR 98015) we finalized our policy to maintain the virtual presence flexibility on a temporary basis, that is, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025 as such a policy continues to support access and preserve workforce capacity.

(1) CY 2026 Direct Supervision in RHCs/FQHCs

We have considered information from interested parties, particularly in response to the CY 2024 PFS proposed rule where we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have regarding this policy.

As discussed in the CY 2025 final rule (89 FR 98014 through 98015), in response to our proposal to extend this definition through the end of 2025, commenters supported the proposal to allow virtual direct supervision through real-time audio/video communications technology in RHCs and FQHCs, citing benefits such as reduced inefficiencies, improved accessibility, better alignment with other outpatient providers, and enhanced healthcare delivery without compromising patient safety or program integrity.

In the CY 2026 PFS proposed rule (90 FR 32556-32557) we explained that given the information presented by interested parties on safety and effectiveness, we believe direct supervision provided via two-way real time audio-video telecommunications technology meets the statutory requirements specific to RHCs and FQHCs at section 1861(aa)(2)(B) of the Act regarding necessary physician supervision and guidance. We noted that for services paid under the PFS, we proposed to permanently adopt a definition of "direct supervision" that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26, except for services that have global surgery indicators of, 010, or 090 (90 FR 32394 and 32395). These indicators are defined in IOM Pub. 100-04, chapter 23, section 50.6 as 010, "Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable"; and 090, "Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount". These are services that describe a surgical service as well as its post-operative period of either 10 days, or 90 days, respectively.

We stated that in the interests of aligning our approach toward direct supervision for RHCs and FQHCs with that for services paid under the PFS, we believed that we should permanently adopt this flexibility in RHCs and FQHCs, as such flexibility continues to support access and preserve workforce capacity. However, we noted that, as we discussed in IOM Pub. 100-02, chapter 13, section 40.4, the Medicare global billing requirements do not apply to RHCs and FQHCs, and global billing codes are not accepted for RHC or FQHC billing or payment. Since services that have global surgery indicators are not applicable in the RHC and FQHC settings, we proposed revisions at § 405.2401(b) to define "Direct Supervision" to mean that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

The following is a summary of the comments we received on the proposal and our responses.

Comment: Commenters supported our proposal to permanently allow “direct supervision” in RHCs and FQHCs through real-time, interactive audio-video technology. Commenters state that this policy will expand access to care, particularly in rural and underserved areas and will address workforce shortages, improve continuity of care, and help modernize service delivery. Several commenters emphasized the benefits of enhanced patient access, physician-led team-based collaboration, and interdisciplinary coordination facilitated by virtual supervision.

Response: We appreciate the support of commenters.

Comment: A commenter requested that CMS permanently amend regulations for RHCs and FQHCs that require physician supervision of nurse practitioners in these facilities, and which do not allow, pursuant to 42 CFR 491.7(a), for an RHC or FQHC to be under the medical direction of a nurse practitioner, even when authorized under state law. The commenter stated these requirements are burdensome and unnecessary.

Response: This comment is out of scope for this final rule because it does not relate to this specific proposal included in the proposed rule, however we appreciate the feedback and may evaluate further.

After consideration of public comments, we are finalizing our proposal to permanently adopt a definition of “direct supervision” that allows "immediate availability” of the supervising practitioner using audio/video real-time communications technology (excluding audio-only). Specifically, we are finalizing revisions at § 405.2401(b) to include a definition of “Direct Supervision” to mean that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

c. Payment for Medical Visits Furnished Via Telecommunications Technology

In the CY 2026 PFS proposed rule (90 FR 32557-32558), we discussed how widespread use of telecommunications technology to furnish services during the PHE has illustrated interest within the medical community and among Medicare beneficiaries in furnishing and receiving care through the use of

technology beyond the PHE. During the PHE, RHCs and FQHCs, much like other health care providers, had to change how they furnish care to meet the needs of their patients. RHCs and FQHCs heavily utilized the temporary authority to be paid for their services when provided as Medicare telehealth services during the PHE. We stated that eliminating flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology for over 5 years and resuming payment solely for in-person, face-to-face medical visits, would cause disruptions in access to services from RHC and FQHC practitioners. This would be particularly problematic for the underserved populations that these settings furnish services to since it could fragment care. We explained that we believe that we need to preserve the flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology temporarily and to do so through an approach that these settings are familiar with to mitigate burden while we consider how to incorporate services furnished through telecommunications technology on a more permanent basis.

For these reasons, in the event that Congress no longer authorized payment to be made for telehealth services furnished via a telecommunications system by RHCs and FQHCs using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS, we proposed, on a temporary basis, to facilitate payment for non-behavioral health visits (hereafter referred to in this discussion as "medical visit services") furnished via telecommunications technology using an approach that closely aligns with this methodology. Like the methodology we used during and after the PHE, we proposed that RHCs and FQHCs would continue, in accordance with 42 CFR 405.2464(g), to bill for RHC and FQHC medical visit services furnished using telecommunications technology, including services furnished using audio-only communications technology, by reporting HCPCS code G2025 on the claim for the period beginning with the PHE for COVID-19 and ending on December 31, 2026. Since the costs associated with medical visit services furnished via telecommunications technology are not included in the calculations for the RHC AIR methodology and FQHC PPS, we proposed the need for a a proxy that would represent such resources used when furnishing these services. Therefore, we proposed, similar to the methodology described in section 1834(m)(8) of the Act, to continue to calculate the payment amount for these services billed using HCPCS code G2025 based on the average amount for all Medicare telehealth services paid

under the PFS, weighted by volume for those services reported under the PFS. We believed that continuing to use this weighted average is appropriate while we contemplate permanent policies for these services since there is a wide range of payment rates for the Medicare telehealth services paid under the PFS. As discussed in the CY 2025 final rule (89 FR 98015 through 98016), we believe that RHCs and FQHCs generally furnish services that are similar to and at a frequency the same as physicians and other practitioners paid under the PFS. While we do not have actual cost information, we believe that this weighted average is an appropriate proxy since it addresses certain resource costs experienced by professionals and would mitigate any potential over or under payments. Costs associated with these services would continue to not be used in determining payments under the RHC AIR methodology or the FQHC PPS. We proposed to facilitate payment for non-behavioral health visits furnished via telecommunications technology and pay for such services in accordance with such methodology through December 31, 2026.

We believe that the proposed approach would preserve the telecommunication technology flexibility under which RHC and FQHC services have been furnished for over 5 years and would not impact access to care for Medicare beneficiaries who currently benefit from these services while CMS contemplates next steps. We noted that this is a temporary stopgap approach to preserve access concerns.

(1) Alternative Payment of Medical Visits Furnished Via Telecommunication Technology

As we discussed in the CY 2026 PFS proposed rule (90 FR 32558), we considered reevaluating the regulations regarding face-to-face visit requirements for encounters between a beneficiary and an RHC or FQHC practitioner in light of contemporary medical practices. That is, we considered proposing a revision to the regulatory requirement that an RHC or FQHC medical visit must be a face-to-face (that is, in-person) encounter between a beneficiary and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time, audio and video telecommunications technology. This would result in payment for services furnished via telecommunication technology to be made under the RHC AIR methodology and under the FQHC PPS, similar to how we revised the regulations for mental health visits. We believe interested parties may prefer the per visit payment that aligns with the RHC AIR or FQHC PPS. However, we did not propose this alternative because we determined that it would have unintended consequences, especially in cases where the RHC AIR or FQHC PPS per-visit rates would be

significantly higher than the PFS rate that would apply if other entities furnished the same service to the same beneficiary in the same location.

We explained that we believe that continuing to pay temporarily for RHC and FQHC services furnished via telecommunication technologies in the same manner as we have done over the past several years preserves the flexibility for RHCs and FQHCs to continue access to care, mitigates administrative burden, and mitigates potential program integrity concerns. However, we solicited comment on the alternative proposal we considered. That is, revising the definition of a visit to include interactive, real-time, audio/video telecommunication technology which would result in a capitated payment under the RHC AIR methodology or FQHC PPS.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported continuing to pay for non-behavioral services in RHCs and FQHCs furnished via telecommunications technology, stressing that virtual care is essential for rural and underserved populations. They highlighted that for many beneficiaries, particularly those who are elderly, homebound, or living in isolated areas, telehealth is not simply a convenience but the only practical way to access care. Several commenters also emphasized the need for CMS to work with Congress to make current flexibilities permanent, including allowing patients to receive telehealth from their homes, to avoid confusion and prevent disruptions in access once temporary waivers expire.

Commenters diverged, however, on how CMS should structure payment. Some commenters supported CMS' proposal to continue to pay RHCs and FQHCs with HCPCS code G2025 which reflects a weighted average of the PFS rates of all services on the telehealth list. MedPAC stated this approach preserves access while preventing unnecessary increases in beneficiary cost-sharing and Medicare spending. They warned that paying higher rates under the RHC AIR and FQHC PPS would not only raise taxpayer costs but could also create incentives for providers to overuse telehealth or shift away from in-person care. They further stated that paying for medical visits furnished via telehealth would often result in beneficiaries and taxpayers paying much more for the same service than they currently do because the FQHC PPS and RHC AIR payment system rates are higher than the PFS-equivalent rate. In addition, because beneficiary coinsurance for services billed under the RHC AIR methodology is set based on RHC charges and not payment rates, rural beneficiaries would experience especially high increases in

coinsurance if CMS switched from paying PFS-equivalent rates to those based on the RHC AIR methodology

Some commenters, in contrast, expressed preference for our alternative approach, arguing that telehealth visits should be paid at the PPS or AIR rates. They emphasized that the costs of operating FQHCs and RHCs such as staffing, facilities, compliance, and IT systems, are the same regardless of whether visits are in person or virtual. The current payment rate for HCPCS code G2025, typically around $90 per visit, was described as inadequate to cover these costs, undermining clinics' ability to sustain telehealth infrastructure in the long term. These commenters argued that treating telehealth visits as full encounters would ensure payment equity, reduce administrative burdens, and support the financial stability of safety-net providers serving the most vulnerable communities.

Response: We recognize that many commenters supported the alternative proposal to permanently redefine an RHC or FQHC "visit" to include audio-video telecommunication technology and to pay such services at the AIR or PPS rates, and reiterate, that our proposal was intended as a temporary, stopgap measure; we believe that continuing to pay for these visits using HCPCS code G2025 which reflects PFS rates is preferable to preserve access to services furnished via telecommunication technologies for beneficiaries, while avoiding sudden payment disruptions to maintain predictability for providers and allowing CMS time to consider permanent policies informed by additional data and experience. Extending this methodology through December 31, 2026 also provides flexibility for CMS to respond to any statutory changes Congress may enact regarding telehealth in these settings.

After consideration of public comments, we are finalizing our proposal to continue to pay for RHC and FQHC medical visit services furnished using telecommunications technology, including services furnished using audio-only communications technology, with HCPCS code G2025 through December 31, 2026 in accordance with § 405.2464(g).

d. Conforming Regulatory Text Changes

Subsequent to the publication of the CY 2025 PFS final rule, section 2207(d) of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended sections 1834(y)(2) and 1834(o)(4)(B) of the Act by extending the delay of in-person requirements for mental health services furnished through telecommunication technology for RHCs and FQHCs, respectively, through September 30, 2025. We

therefore proposed to make conforming regulatory text changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,' we proposed to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we proposed to amend paragraph (d). Both of these provisions would require that, beginning October 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

Comment: Some commenters requested that these in-person requirements continue to not apply beyond 2025, stating that many patients seen virtually are at a distance that would make an in-person session impossible.

Response: After considering public comments, we are finalizing technical changes to the regulatory text that we believe more closely align with statutory requirements. Specifically, we are amending the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,' we proposed to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' to clarify that the in-person visit requirements will not apply to any services furnished before October 1, 2025.

We wish to clarify that the intent of these edits is solely to conform the regulations to the statutory delay of the in-person visit requirements prior to October 1, 2025. More broadly, we believe it is important to maintain consistency across care settings when applying requirements of this nature. CMS will address the approach to these in-person visit requirements for RHCs and FQHCs in future guidance.

Comment: Some commenters requested that CMS extend the delay of the implementation of these requirements specifically for Certified Community Behavioral Health Clinics (CCBHCs), Community Mental Health Centers (CMHCs), and other licensed behavioral health clinics beyond 2026.

Response: These comments are out of scope for this final rule because they do not relate to this specific proposal included in the proposed rule.

After consideration of comments, we are finalizing revisions to 42 CFR part 405, subpart X, specifically, at § 405.2463(b)(3), ''What constitutes a visit,'' and, at § 405.2469(d), ''FQHC supplemental payments,'' to clarify that the in-person visit requirements will not apply to any services furnished before October 1, 2025.

e. Miscellaneous Comments

We received several comments that were out of scope from what we proposed in the CY 2026 PFS final rule for RHCs and FQHCs. The following is a summary of the comments we received and our response.

Comment: A few commenters suggested that CMS amend § 405.2463(c)(1)(iii) to allow RHCs to bill a medical or mental health visit and an Annual Wellness Visit (AWV) separately when furnished on the same day and allow RNs to furnish and bill AWVs. If this is not feasible, commenters suggested CMS consider, at minimum, an add-on payment when an AWV is performed on the same day as a medical visit. Some commenters requested that CMS permit RHCs to bill and receive an additional payment for HCPCS code G2211 like practitioners that are paid under the PFS, which they believe would fully account for additional time, intensity, and practice expense inherent to the longitudinal care that HCPCS code G2211 was designed to capture. A commenter recommended that CMS evaluate the adequacy of the RHC AIR and FQHC PPS base rates under the Medicare Economic Index (MEI) methodology and consider supplemental adjustments where necessary to support the long-term sustainability of these safety-net providers. Another commenter would like to see simplified billing or bundled options for any new codes to reduce administrative barriers for RHCs that may not have dedicated billing staff. A commenter recommended that CMS conduct an evaluation to separately pay medical nutrition therapy (MNT) services from the RHC AIR and FQHC PPS to better support the scope and value of these services. A few commenters wanted CMS to support healthcare in rural settings by allowing registered nurses (RNs) to bill the CPT codes for care coordination. A commenter would like CMS to permit pharmacists the authority to bill directly under Medicare and not refer to pharmacists as "auxiliary personnel" as they play a role behind the scenes for care coordination services.

Response: We thank the commenters for their feedback; however, these comments are outside the scope of what we proposed for CY 2026 for RHCs and FQHCs. We will take these comments into consideration for further evaluation.

C. Ambulatory Specialty Model (ASM)

1. Overview of Ambulatory Specialty Model

a. Introduction

Under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center) in section 1115A(b) of the Act, we proposed the implementation and testing of the Ambulatory Specialty Model (ASM), a new mandatory alternative payment model with 5 performance years that would begin January 1, 2027, and end December 31, 2031. ASM will test whether adjusting payment for specialists based on their performance on targeted measures of quality, cost, care coordination, and meaningful use of certified electronic health record (EHR) technology (CEHRT) results in enhanced quality of care and reduced costs through more effective upstream chronic condition management.

To enhance quality of care and lower the costs of care, ASM will be established as a mandatory model focused on the care provided by select specialists to Medicare beneficiaries with the chronic conditions of heart failure and low back pain. Under the model, clinicians will be required to report a select set of measures and activities clinically relevant to their specialty type and the chronic condition of interest. These measures and activities will assess quality, cost, interoperability, and care coordination practices, all of which are necessary for effective upstream chronic condition management. To incentivize improvements in quality and care coordination, CMS will assess the clinician's performance on those measures and activities relative to their peers, who are also participants of the model and of a similar specialty type treating the same chronic condition.

ASM falls within a larger framework of activities initiated by the Innovation Center to focus on high-volume, high-cost chronic conditions and direct engagement of specialists in value-based payment. The Innovation Center recently announced its new strategy based on three strategic pillars for improving the health of Americans and protecting taxpayers: preventing disease through evidence-based practices, empowering people with information to make better decisions, and driving choice and competition.[156]

In line with the updated Innovation Center principles, this final rule finalizes a new mandatory model that we believe will improve beneficiary and provider engagement, incentivize preventive care,

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[156] CMS Innovation Center, CMS Innovation Center 2025 Strategy to Make America Healthy Again, May 2025. *https://www.cms.gov/priorities/innovation/about/strategic-direction#:~:text=Three%2DPronged%20Approach,served%20by%20the%20Innovation%20Center*.

and increase financial accountability for certain specialists. The model will build upon lessons learned from previous Innovation Center models and the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program. We believe the model will answer the call to create a more cohesive and efficient health system that enhances the quality of care and reduces costs over time. To promote preventive care, the model will incentivize specialists who are ASM participants to ensure that their patients have a regular source of primary care and are screened to help identify risks and early signs of chronic conditions. This model will also seek to prevent deterioration and complications associated with established chronic conditions. To empower patients, the model will promote direct accountability for the quality of specialty care specific to heart failure and low back pain. By featuring patient-reported outcome measures in the finalized quality ASM performance category, this model encourages patients to report their improvement or decline in function, which directly impacts clinician payment and further incentivizes clinicians to incorporate patient voice and experience in clinical care decisions. We believe a focus on patient-reported measures elevates patient voice, leading clinicians to be more responsive to the patient's response to treatment, while also addressing the significant spending that results from functional impairment. These measures also provide a pathway for clinicians to have conversations about non-medical, lifestyle-based interventions with their patients. This finalized model is intent on removing the onus from patients with heart failure and low back pain to act as the go-between among clinicians they see for their care by incentivizing clinicians, specifically specialists, to coordinate care for their patients more seamlessly. For this reason, we believe that patients will be able to focus on solutions to their health, rather than resolving information and guidance they have received from multiple clinicians.

Finally, the model will require the participation of individual clinicians rather than organizations to encourage competition and create a level playing field for solo and small practices. By evaluating clinicians individually, ASM removes the unequal reporting and scoring benefits that have been previously afforded to consolidated health systems and group practices. This form of mandatory participation will bring transparency, accountability, and comparability at the clinician-level, helping to identify clinicians within large, consolidated health systems or provider networks providing low-value care.

Low-value care refers to services that: (1) may offer limited or no clinical benefit to a patient; or (2) may present risks of harm that outweigh the potential benefit. By requiring the participation of individual clinicians, we believe this model will reduce spending that represents low-value services and major cost-drivers for heart failure and low back pain (for example, unnecessary imaging, surgeries, hospital admissions). Ultimately, this model aims to drive competition among similar specialists with a targeted assessment of their performance relative to their peers in the treatment of a specific chronic condition and protect taxpayers by reducing low-value services by holding specialists accountable for the cost of services clinically related to their role in managing care.

We have designed ASM with a focus on clinicians who commonly treat patients in an ambulatory setting, develop longitudinal relationships with patients, and co-manage beneficiaries with primary care providers (PCP). In addition, we considered those who treat chronic conditions that are likely to benefit from improved integration between specialty and primary care to maximize opportunities for incentivizing high-value care and tertiary prevention. Specifically, we proposed to focus the model on the chronic conditions of heart failure and low back pain, as they have previously established episode-based cost measures (EBCMs) specified for the MIPS cost performance category.

The EBCMs were developed with specialists and interested parties through an extensive, collaborative process that, by design, focused on conditions with a large share of Medicare spending, a high number of responsible clinicians, and opportunities for care improvement. Based on recent estimates, heart failure and low back pain, in particular, account for 3.5 and 2.7 percent total Medicare Part A and B spending.[157] These are significantly higher than other chronic conditions with EBCMs, which account for less than one percent of Medicare Part A and B spending, except for diabetes, which accounts for 4.2 percent of spending.[158] In contrast, many Medicare beneficiaries with type 2 diabetes are capably managed by primary care physicians as the quarterback of their care with input from consulting specialists. Consequently, we do not believe it is an appropriate chronic condition for this specialty care model.

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[157] Quality Payment Program, 2025 Summary of Cost Measures, December 2024. *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3129/2025-mips-summary-cost-measures.pdf*.
[158] Ibid.

ASM will be a mandatory model that begins on January 1, 2027 and ends December, 31, 2033. There will be 5 performance years, beginning January 1, 2027 and ending December 31, 2031. Final data submission of measures and activities will be in CY 2032, with final model payment adjustments in CY 2033.

To measure clinician performance in ASM, we will establish a mandatory set of measures and activities for physicians that meet the proposed ASM participant eligibility criteria described in section III.C.2.c.(3) of this final rule. ASM aims to assess the quality and cost performance of ASM participants providing care for Medicare beneficiaries with the targeted chronic conditions at the individual clinician level (TIN/NPI) while measuring practice transformation and interoperability strengthening at the group level. Specifically, ASM will test whether adjusting Medicare Part B payments for covered professional services based on measures of quality, cost, care coordination, and CEHRT results in enhanced quality of care and reduced costs through more effective upstream chronic condition management.

ASM will leverage components of the existing MIPS Value Pathway (MVP) framework, as appropriate, to meaningfully engage specialists in improving the quality of care for high-volume, high-cost chronic conditions and better integrate specialists in primary care. MVPs are one MIPS reporting option that provides a smaller set of measures to choose from that are most relevant to a condition or specialty. Currently, for MIPS, CMS assesses the performance of each MIPS eligible clinician on measures and activities CMS has specified for a CY performance period/MIPS payment year for four performance categories: quality, cost, improvement activities, and Promoting Interoperability (which refers to the meaningful use of Certified Electronic Health Record Technology (CEHRT). In accordance with section 1848(q) of the Act, CMS calculates a composite performance score (a "final score" as defined at 42 CFR 414.1305) from 0 to 100 points for each MIPS eligible clinician. Then, CMS compares each MIPS eligible clinician's final score to the performance threshold established in prior rulemaking for that CY performance period/MIPS payment year to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act. For the applicable MIPS payment year, CMS calculates and applies to each MIPS eligible clinician: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS

payment adjustment factor for each MIPS eligible clinician, CMS accounts for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act.

By applying these budget neutrality and scaling factor requirements, CMS' calculations of positive MIPS payment adjustment factors for each MIPS eligible clinician are limited by CMS' calculations of negative MIPS payment factors for each MIPS eligible clinician. In other words, CMS' estimated amounts of positive MIPS payment adjustment factors for MIPS eligible clinicians performing above the performance threshold must be offset by CMS' estimated amounts of negative MIPS payment adjustment factors for MIPS eligible clinicians performing below the performance threshold. In MVPs, however, clinicians still have flexibility to select which measures to report. Under MIPS, a clinician's performance is assessed against all MIPS clinicians, regardless of reporting option, specialty type, or the services they provide.

As CMS discussed in a 2024 Request for Information (RFI) (89 FR 61596),[159] we expect that a more targeted approach where clinicians are evaluated: (1) on required reporting of a set of relevant performance measures; and (2) among clinicians furnishing similar sets of services, will produce scores and subsequent payment adjustments that are more reflective of clinician performance. We believe that a more targeted approach to measurement will also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. This targeted approach will include reporting or required collection of patient-reported outcome measures that assess the change in a beneficiary's functional status over the course of the episode, ensuring clinicians prioritize the same goals as their patients. Furthermore, equipped with more specialty-relevant performance information, we expect clinicians will be more likely to invest resources in pursuit of better outcomes and improved care coordination, ultimately resulting in better care for patients. To test this more targeted approach, this finalized mandatory model leverages the existing MVP policies, deviating from MVP policies in specific ways, as applicable.

First, unlike the voluntary measure and activity selection permitted under the MVP reporting option, ASM will require clinicians to report on a set of measures and activities clinically relevant to their

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[159] Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Medicare Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments.

specialty type and the chronic condition of interest. This will ensure a more analogous comparison between clinicians. Second, while clinicians reporting under MVPs are scored against the entire pool of MIPS clinicians, ASM will assess performance against only those clinicians treating the same chronic condition. Each clinician will receive a performance score based on the measures and activities included in the four ASM performance categories (which are based on the MIPS performance categories)—quality, cost, improvement activities, and Promoting Interoperability. In section III.C.2.d. of this final rule, we describe the finalized requirements in the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories.

Third, we will use a different approach, compared to MVPs, for aggregating the ASM performance categories to calculate a final score and determine the ASM payment adjustment. This approach will broaden the distribution of final scores and increase the magnitude of payment adjustments, which we believe will incentivize performance improvements that will lead to more effective upstream chronic condition management. We refer readers to the CY 2022 PFS final rule for additional details on the MVP performance category weighting § 414.1365(e). As described in section III.C.2.e. of this final rule, we will focus on value and variation in clinician performance by primarily measuring performance on quality and cost performance categories for calculating the ASM final score. We also understand the importance of the improvement activities and Promoting Interoperability performance categories and will apply potential negative scoring adjustments for non-reporting or poor performance. We are also finalizing positive scoring adjustments for clinicians in small practices participating in the model and for ASM participants treating a large proportion of medically complex patients. We refer readers to sections III.C.2.c., III.C.2.d., and III.C.2.e. of this final rule for additional details on the finalized policies related to ASM participant eligibility criteria, the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories, and ASM final scoring calculations.

To ensure savings in the financial impacts for the model, ASM will also retain a percentage of the payments rather than distributing all funds as clinicians' payment adjustments. ASM participants will receive neutral, negative, or positive payment adjustments on future Medicare Part B payments for covered professional services based on their performance during an ASM performance year. As is done under MIPS, clinicians participating in ASM will continue to bill Medicare under the traditional fee for

service (FFS) system for services furnished to Medicare FFS beneficiaries. MIPS eligibility criteria described under 42 CFR 414.1305 are not factored into the ASM participant eligibility criteria described in section III.C.2.c.(3) of this final rule. However, MIPS eligible clinicians participating in this model will be exempt from MIPS reporting requirements for any ASM performance year that they are included in ASM.

b. Background

Health care is becoming more fragmented as Medicare beneficiaries are increasingly seeing a greater number of specialists on a more regular basis. At the same time, the volume of primary care visits has remained relatively constant.[160,161] Primary care teams must now coordinate with more specialists than ever before,[162] despite persistent barriers to specialist access for certain patients.[163,164] We believe there are opportunities to improve coordination between specialists and PCPs and increase beneficiary engagement in care decisions, particularly with respect to preventing the onset and progression of disease.

Although the Innovation Center has tested models that address the integration of primary and specialty care for chronic conditions that may benefit from greater collaboration and create opportunities for preventive care, these models have been largely focused on behaviors and practice patterns in primary care.[165] This model test elects to focus on the behaviors and practice patterns in specialty care for those treating chronic conditions and would be the first Innovation Center model to use the MVP framework as the foundation for a model test.

We believe the MVP framework has many benefits. First, the MVP framework advances value-based care by narrowing the available measure set based upon clinician specialty, medical condition, or patient population, which allows for meaningful comparisons to be made across providers and relevant

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[160] Barnett ML, Bitton A, Souza J, Landon BE. Trends in Outpatient Care for Medicare Beneficiaries and Implications for Primary Care, 2000 to 2019 [published correction appears in Ann Intern Med. 2022 Oct;175(10):1492]. Ann Intern Med. 2021;174(12):1658-1665. doi:10.7326/M21-1523.

[161] Lori Timmins, PhD, Carol Urato, MA, Lisa M. Kern, MD, MPH, Arkadipta Ghosh, PhD, Eugene Rich, MD. Primary Care Redesign and Care Fragmentation Among Medicare Beneficiaries. The American Journal of Managed Care, March 2022, Volume 28, Issue 3.

[162] The CMS Innovation Center's strategy to support person-centered, value-based specialty care. 2022. Retrieved from https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.

[163] McConnell KJ, Charlesworth CJ, Zhu JM, Meath THA, George RM, Davis MM, Saha S, Kim H. Access to Primary, Mental Health, and Specialty Care: A Comparison of Medicaid and Commercially Insured Populations in Oregon. J Gen Intern Med. 2020 Jan;35(1):247-254. doi: 10.1007/s11606-019-05439-z. Epub 2019 Oct 28. PMID: 31659659; PMCID: PMC6957609.

[164] Romaire MA, Haber SG, Wensky SG, McCall N. Primary care and specialty providers: an assessment of continuity of care, utilization, and expenditures. *Med Care*. 2014;52(12):1042-1049. doi:10.1097/MLR.0000000000000246.

[165] See the evaluation reports of the Comprehensive Primary Care Plus (CPC+) model, which ran from 2017 to 2021, https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus. See also the evaluation reports of the Primary Care First (PCF) model, which began in 2021 and will end December 31, 2025, https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options.

feedback to be available to participants on their performance, strengthening the foundation for accountability in specialty care. The MVPs utilize a cohesive set of measures and activities focused on performance in rendering care for a particular specialty or clinical condition. Second, we believe that meaningful comparisons of performance combined with a payment methodology that includes more significant Medicare Part B payment adjustments, will encourage meaningful specialty care engagement with PCPs to both prevent and manage the onset of chronic conditions. Third, we intend to test ASM's more targeted approach to performance assessment, as described in the introduction section of this final rule, so it may provide a foundation to potentially expand this approach to other specialist cohorts treating other chronic conditions. While there are twenty-one MVPs for the CY 2025 performance period/2027 MIPS payment year spanning numerous specialties, CMS has a goal of creating additional MVPs relevant to the practices of 80 percent of MIPS eligible clinicians. The MVP reporting option, with its focused set of measures and activities aligned around specific specialties or conditions, provides a framework for applying ASM's targeted approach to other specialist cohorts treating other chronic conditions. Using an existing framework that is agnostic to specialty type, as opposed to creating multiple unique models that are each narrowly defined by a condition or specialty, will allow the Innovation Center to take a more inclusive and unified approach to increasing specialist engagement in value-based payment.

Using MVPs as a framework to test a chronic condition model, ASM will increase the number of specialists in value-based care arrangements and hold them accountable for ensuring beneficiaries have a regular source of primary care. Through required improvement activities and measures, the model will also encourage specialty care providers to actively engage with both beneficiaries and PCPs to improve care transitions and make certain their patients are receiving preventive care, such as screening for obesity and depression. When primary and specialty care providers collaborate across care settings, together they can deliver accountable care that best meets patients' needs and preferences.

We received several comments about ASM's clinical focus on heart failure and low back pain. The following is a summary of these comments and our responses.

Comment: A few commenters supported ASM because of the focus on value-based care for high-cost conditions like heart failure and low back pain, citing the importance of potential improvements in care quality, cost reduction, and specialist engagement. Several commenters

supported the proposed chronic disease focus of ASM since heart disease and low back pain are leading causes of hospitalizations, readmissions, and high costs in the United States where care fragmentation can negatively impact patient outcomes; a commenter believes that ASM can be a critical step for addressing chronic illness burden. A few commenters commended the model's engagement of independent clinicians.

Response: We appreciate the commenters' support of ASM, including its focus on heart failure and low back pain. We agree that ASM creates opportunities for increasing specialist participation in value-based care to create improvements in care quality and reductions in cost. We also appreciate commenters' support for a model that engages independent clinicians.

Comment: A few commenters did not support the proposed focus on low back pain for ASM because of the broad and diverse range of specialties that care for low back pain at different stages of disease progression. Another commenter shared a concern with the focus on low back pain because it can often be a symptom of a variety of underlying clinical diagnoses and treating it as a single condition ignores physiological aspects of the disease, increases heterogeneity of patients, and underestimates the complexity of evaluating and treating the underlying diseases that cause low back pain.

Response: We appreciate commenters' feedback on including low back pain as a chronic condition of focus in ASM. As we discuss in section III.C.2.c.(2).(b) of this final rule, we believe that several types of specialists can be held accountable for ongoing chronic condition management for low back pain. In the CY 2026 PFS proposed rule, we proposed to include these relevant specialty types in our ASM participant eligibility criteria to identify low back participants; we proposed to include anesthesiology, pain management, interventional pain management, neurosurgery, orthopedic surgery, or physical medicine and rehabilitation clinicians in the low back pain ASM cohort (90 FR 32564). We agree that low back pain can often be a symptom of other underlying clinical diagnoses; however, as many patients receive low back pain care from specialists, in addition to care for underlying and contributing

diagnoses, we believe increasing accountability for low back pain care management presents opportunities for improving patient outcomes regardless of the heterogeneity of patients receiving care for low back pain. We believe that the collective measurement framework for low back pain will comprehensively evaluate the quality and cost of care related to low back pain regardless of the physiological aspects or complexity of the causes of low back pain, while creating incentives for practice improvements, such as stronger integration with PCPs and improving interoperability of EHRs.

Comment: A commenter acknowledged that heart failure and low back pain are significant chronic conditions, but requested more specific reasoning, information and justification for why heart failure and low back pain were selected as the focus of the model when other conditions may similarly satisfy the goals of the model.

Response: We appreciate this commenter's request for additional information and justification as to why heart failure and low back pain were selected for the model. We believe that low back pain and heart failure serve as ideal cohorts for ASM because these chronic conditions, in particular, present clinical complexity, financial impact, measurable outcomes, and improvement opportunities while maintaining sufficient volume and predictability for successful model implementation and evaluation. Heart failure affects millions of Americans and is one of the leading causes of Medicare hospitalizations. It accounts for significant Medicare spending due to frequent readmissions and complex care needs. Low back pain is one of the most common reasons for physician visits and disability claims. It, too, is the cause of substantial healthcare spending. Both conditions have well-defined roles for the specialists that treat them, clear quality measures and treatment pathways that can be measured and improved. Both conditions present opportunities for improvement with strong coordination between specialty and primary care. We believe both heart failure and low back pain will provide lessons learned for other chronic conditions. The model could expand to other chronic conditions if success in quality

improvement and cost reduction is found with the treatment of heart failure and low back pain under the parameters of ASM.

Comment: Several commenters offered feedback on alternative chronic conditions, such as chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD) for inclusion in ASM.

Response: We appreciate commenters for their feedback on other chronic conditions that may be suitable for inclusion in ASM. We did not consider COPD or CKD, and their related specialties, for inclusion in ASM at this time. Should we consider expanding ASM to include additional chronic conditions, we would do so through notice-and-comment rulemaking.

Comment: A commenter recommended that CMS should provide additional details on how "low value" services within ASM are defined to ensure complex patients are not excluded from appropriate interventions.

Response: We appreciate the commenter for their input. For the purposes of ASM, low-value care refers to services that: (1) may offer limited or no clinical benefit to a patient; or (2) may present risks of harm that outweigh the potential benefit.

We also received several comments about making ASM a voluntary model instead of mandatory. The following is a summary of these comments and our responses.

Comment: Several commenters recommended that CMS ensure ASM is voluntary, patient-centered, and adequately resourced to avoid unintended negative impacts on clinicians and patient access to care. A few commenters recommended exploring voluntary, evidence-based alternatives, tied to stronger evidence of potential patient benefits.

Response: We appreciate commenters for their suggestion to make ASM voluntary. As we discuss in this section and in section III.C.2.c.(1) of this final rule, we believe mandatory participation is necessary to test ASM due to concerns that selection bias in a voluntary model would undermine ASM's incentives. Furthermore, we are finalizing several provisions that we believe will help avoid unintended negative impacts on clinicians and patient access to care. Such provisions include, but are not limited to, not subjecting ASM participants to payment

adjustments if they cannot meet case minimums for required quality and cost measures, providing scoring adjustments to ASM participants that serve a high volume of medically or socially complex patients, and providing advance notification of mandatory participation to allow participants time to prepare. Several features of this model are patient-centered, including incorporating patient voice into quality measurement through patient-reported outcome measures and beneficiary incentives that can support upstream chronic condition management for heart failure and low back pain. As with all Innovation Center models, we will also monitor for potential unintended consequences and adjust model designs as necessary.

Comment: Many commenters advised CMS to pause implementation, collaborate with specialty societies, and redesign the model to better support specialists in voluntary and patient-centered models. A few commenters recommended pilot programs or iterative testing instead of mandatory participation.

Response: We appreciate the commenters for their feedback. As part of ASM's design, we received feedback from many interested parties. We received input from public comments to the 2024 Request for Information (RFI) (89 FR 61596), which included input from interested parties, provider groups, specialty societies, health systems, academics, and others. We believe that ASM's design incorporates feedback received by interested parties that allows for a reliable model test. We refer readers to section III.C.2.c.(1) of this final rule for more discussion on the rationale for ASM's mandatory nature.

We received several comments about ASM's alignment with the Quality Payment Program's MVP framework. The following is a summary of these comments and our responses.

Comment: Several commenters broadly support the goals of ASM but recommended CMS to closely monitor the Quality Payment Program MVP framework and other value-based care models to incorporate lessons-learned to mitigate potential unintended consequences of the model.

Response: We appreciate the commenters' support for ASM's goals. We discuss throughout this section and in section III.C.2.d of this final rule, ASM's performance

measurement approach and our rationale for aligning with the MVP framework. We believe that the MVP framework advances value-based care by narrowing the available measure set based upon clinician specialty, medical condition, or patient population, which allows for meaningful comparisons to be made across clinicians. We have collaborated with the Quality Payment Program in the development of ASM and will continue to do so throughout the implementation of ASM to ensure appropriate alignment. As part of the ecosystem of condition-specific value-based care models, we also intend to learn from other models' implementation experiences to adjust ASM requirements if the need arises. As part of our monitoring and evaluation efforts, we will also monitor unintended consequences and adjust ASM's design if necessary.

Comment: Many commenters shared concerns and made recommendations about ASM's design about the reliance on the MVP framework and that ASM would not provide an on-ramp into Advanced APMs. A few commenters supported building off the MVP framework, which may offer a scalable approach to specialty model designs.

Response: We appreciate the commenters who voiced support for ASM building off the MVP framework. We also appreciate the commenters for their recommendations and for detailing their concerns about relying on the MVP framework, especially when it would not provide an on-ramp into Advanced APMs. While the concern about ASM not providing a direct on-ramp to Advanced APMs for individual clinicians is valid, it should not overshadow the substantial value that ASM provides in building the foundational capabilities necessary for successful value-based care participation. ASM participation should be considered as one component of a comprehensive value-based care strategy. Organizations should leverage clinician participation in ASM to build internal capabilities while simultaneously pursuing other pathways to Advanced APM participation. This multi-pronged approach maximizes the benefits of current opportunities while positioning ASM participants for future Advanced APM success.

We received comments concerning participant burden that may be introduced by ASM. The following is a summary of these comments and our responses.

Comment: Many commenters emphasize the need for refinement to avoid unintended negative impacts on providers and patients. While ASM's goals are broadly supported, many commenters voiced concerns with administrative complexity and burden on clinicians at a time of workforce shortages, limited evidence of effectiveness of the model on improvement of health outcomes, and the mandatory nature of the model tied to a "tournament model" and potential financial penalties.

Response: We appreciate comments highlighting the concern of providers' burden with participating in ASM. We acknowledge that healthcare providers face many administrative burdens, and that workforce shortages can make additional requirements particularly challenging. The timing of new model implementation during staffing constraints is a legitimate operational concern. For this reason, ASM will not be implemented until January 1, 2027, and data submission for the model will not be required until the first quarter of 2028. Additionally, we will make every effort to alleviate provider burden with robust technical support and implementation guidance.

Comment: A commenter expressed concerns about ASM, noting that it could unintentionally encourage further consolidation in the health care market. The commenter also shared their belief that the financial and administrative burdens associated with ASM may push independent practices to join larger hospital systems or networks.

Response: We appreciate the commenter for stating their concern that ASMs may encourage independent practices to consolidate. However, we disagree because many of the clinicians that will be selected for participation in ASM, including those in independent practices, have experience with other value-based purchasing programs, such as MIPS, or alternative payment models, such as participating in an ACO, and likely have processes in place that can be used to meet ASM data submission requirements. Furthermore, as described in section III.C.2.e.(4) of this final rule, we provide a positive scoring adjustment to recognize the unique challenges faced by smaller and oftentimes independent providers to provide guardrails.

We received several comments about the effects of ASM on participants in small practices, rural areas, or that serve medically and socially complex patient populations. The following is a summary of those comments and our responses.

Comment: Several commenters raised concerns that participation in ASM could potentially negatively impact solo and small practices, safety net providers, and other vulnerable providers because of mandatory participation and the high financial risk associated with ASM. Many commenters emphasized that participation in ASM must be matched with adequate financial and technical support from CMS to avoid undermining its goals

Response: We appreciate the commenters for raising their concerns related to participation of small practices and safety net providers in ASM. We recognize that these types of clinicians and practices have specific challenges that may make it more difficult for more of them to perform well in ASM without additional support. For these reasons, ASM will include specific positive scoring adjustments for ASM participants who we determine have a high degree of medically or socially complex patients, as well as scoring adjustments for participants in small practices or who are solo practitioners. We note that eligibility for these scoring adjustments would be evaluated separately, so ASM participants can qualify for both the complex patient scoring adjustment and small practice scoring adjustment. We refer readers to sections III.C.2.e.(3) and III.C.2.e.(4) of this final rule for further discussion on these provisions. While we did not consider specific financial support to any ASM participant (for example, an upfront infrastructure payment), we note that we will provide advanced notification of mandatory participation for the first ASM performance year beginning in CY 2027 and intend to provide educational resources in CY 2026 to help ASM participants prepare for ASM's requirements.

Comment: Several commenters recommended that CMS refine ASM to better reflect the realities of rural healthcare delivery and recommended that CMS provide targeted support to rural practices, help rural providers develop infrastructure and care partnerships for care coordination, and limit the administrative and financial burdens associated with participation in ASM. Another commenter advised CMS to provide adequate risk adjustment for rural populations. A commenter noted that often rural areas lack the broadband and high-speed

internet infrastructure necessary to support telehealth and other technology-dependent components of ASM. A few commenters voiced concerns that mandating participation in ASM may force small, rural practices to close or consolidate into hospital-affiliated systems, which may reduce patient access to specialists or reduce competition and increase costs for beneficiaries.

Response: We appreciate the commenters for raising feedback about participation of rural clinicians in ASM. We recognize that these types of clinicians and practices have specific challenges that may make it more difficult for more of them to perform well in ASM without additional support. For these reasons, ASM will include several scoring adjustments for which we believe rural ASM participants would likely be eligible. While we did not propose a rural-specific scoring adjustment, as we discussed in the CY 2026 PFS proposed rule (90 FR 32604), we observed that a high proportion of likely ASM participants in small practices were in rural areas, and that an additional rural adjustment on top of small practice scoring adjustments would potentially be duplicative and inappropriately skew the distribution of final scores. We also believe that some rural ASM participants will also qualify for the complex patient scoring adjustment. We refer readers to sections III.C.2.e.(3) and III.C.2.e.(4) of this final rule for further discussion on the small practice and complex patient scoring adjustments and how we expect some rural ASM participants to qualify for this adjustment. As part of ASM's monitoring efforts, we will monitor potential challenges for rural ASM participants and adjust ASM's provisions if necessary.

While we acknowledge the challenges that clinicians in rural areas may have in high-speed internet infrastructure and their ability to provide telehealth, we note that ASM does not require use of telehealth; ASM offers a telehealth waiver as described in section III.C.2.h.(3) of this final rule. ASM will require all participants to meet Promoting Interoperability requirements as described in section III.C.2.d.(5) of this final rule. We note that MIPS does not provide a specific Promoting Interoperability exception for eligible clinicians in rural practices; however, they may qualify for other Promoting Interoperability reweighting should they qualify as small practices as described at § 414.1380(c)(2)(ii)(G). For these reasons and because we account for the Promoting Interoperability ASM performance category score through a possible negative scoring adjustment of up to 10 points to the final score, we believe that the small and solo positive scoring adjustment of 10 or 15 points, respectively, would likely offset any

reductions in scores that a rural ASM participant may receive because of ASM's Promoting Interoperability requirements. As we discuss in section III.C.2.e.(4) of this final rule, we will monitor the sufficiency of these scoring adjustments throughout ASM's model test period.

We appreciate the commenters for sharing their concern that ASM may encourage independent rural practices to consolidate or lead to practice closures. However, we disagree because many of the clinicians that will be selected for participation in ASM, including those in independent practices, have experience with other value-based purchasing programs, such as MIPS, or alternative payment models, such as participating in an ACO, and likely have processes in place that can be used to meet ASM data submission requirements. While we acknowledge that ASM will introduce new requirements, we believe that clinician-level measurement and incentives are important for increasing accountability for chronic condition management for conditions like heart failure and low back pain. Further, we specifically designed ASM with several features to support diverse practice participation, including advanced notification of mandatory participation, scoring adjustment mechanisms, and planned technical resources. We believe these design elements help address the commenters' concerns while maintaining the model's core objective of improving care quality and reducing costs for Medicare beneficiaries.

Comment: Many commenters provided feedback on the technology and infrastructure implementation required to meet ASM requirements. A few commenters voiced concerns and challenges associated with meeting interoperability and other program requirements at an individual clinician or small group practice level. A few commenters noted their belief that meeting interoperability requirements can threaten the financial viability of some practices, especially small practices. A commenter noted that if patient-reported outcome measures (PROs) are central to the future of the model, some clinicians will need to build an infrastructure to support the collection and analysis of data.

Response: We appreciate commenters' feedback regarding the challenges associated with meeting interoperability requirements of the model. We believe investment in interoperability is

a strategic imperative that enables healthcare organizations and their clinicians to deliver better patient care, operate more efficiently, and succeed in value-based care arrangements. We believe investing in interoperability could vastly improve outcomes and operational efficiency, laying the foundation for sustainable healthcare delivery. We acknowledge the upfront costs of interoperability can be significant, particularly for smaller practices, and so, we have designed the payment methodology to account for this potential challenge. The Promoting Interoperability performance category accounts for only a fraction of the final score from which the ASM payment adjustment is calculated. As described in section III.C.2.e of this final rule, final scores in ASM will be calculated based on equal weighting of quality (50 percent) and cost (50 percent) performance categories with potential for negative scoring adjustments based on improvement activities (up to negative 20 points) and Promoting Interoperability (up to only negative 10 points) performance category scores. Furthermore, ASM participants in practices between 2 to 15 total clinicians will also receive an automatic 10-point positive adjustment on their final score; solo practitioners receive an automatic 15-point positive adjustment on their final score. If an ASM participant is unable to meet ASM's interoperability requirements and is in a small practice, the small practice scoring adjustment negates the penalty of not meeting interoperability requirements in the model.

We received several comments and suggestions on providing guidance and support to ASM participants before and during ASM's implementation. The following is a summary of those comments and our responses.

Comment: Several commenters recommended that CMS provide more guidance to interested parties about the model structure and requirements for ASM participants. A few commenters recommended that CMS provide resources to ASM participants to increase their preparedness, specifically by offering technical assistance, including a preview of model results for claims-based measures and providing baseline performance reports for ASM EBCMs prior to the start of the first ASM performance year.

Response: We appreciate commenters for their suggestions for providing more guidance on ASM's requirements to interested parties and participants. We intend to provide publicly available educational resources for ASM participants in CY 2026 to help participants prepare for meeting model requirements beginning in CY 2027. We will also respond to email or phone inquiries related to ASM: AmbulatorySpecialtyModel@cms.hhs.gov, or 1-844-711-2664 (Option 4). We also appreciate the suggestions related to baseline data and ongoing performance data that could be shared with ASM participants. We refer readers to section III.C.2.j. of this final rule for further discussion on the types of data sharing and data feedback that we intend to provide ASM participants once ASM begins.

Finally, we received comments providing suggestions on how we should engage interested parties in the implementation of ASM. The following is a summary of those comments and our responses.

Comment: A few commenters recommended collaborating with patients who live with the chronic condition relevant to ASM. A few commenters recommended ongoing interested parties engagement with specialty societies and practicing clinicians.

Response: We appreciate commenters for the suggestions on possible interested parties engagement approaches as we implement ASM. We intend to engage with specialty societies and groups that represent patients living with heart failure and low back pain as part of ASM's ongoing implementation.

We refer readers to the remainder of ASM's section of this final rule for detailed discussion on comments we received on specific proposals, our responses to those comments, and our finalized provisions and policies for ASM.

2. Provisions of the Ambulatory Specialty Model

a. Definitions

In the CY 2026 PFS proposed rule (90 FR 32561), we proposed at 42 CFR 512.705 to define certain terms for ASM. We described the proposed definitions in context throughout section III.C.2 of the CY 2026 PFS proposed rule. We proposed to codify the definitions and policies of ASM at 42 CFR part 512 subpart G. In addition, we proposed that the definitions contained in the standard provisions for

mandatory Innovation Center models at subpart A of part 512 would also apply to ASM, unless expressly stated otherwise in the policies set forth at § 512.705 through § 512.780. We sought comments on the proposed definitions for ASM and respond in context throughout section III.C.2 of this final rule.

b. Length of Model Test

In the CY 2026 PFS proposed rule (90 FR 32561 through 32562), we proposed to define the "ASM test period" as the 7-year period from January 1, 2027 to December 31, 2033 that includes all ASM performance years and ASM payment years as described in Table B-D1. We proposed at § 512.705 to define "ASM performance year" as a 12-month period beginning on January 1 and ending on December 31 for each year of the first 5 calendar years of the ASM test period. We proposed at § 512.705 to define an "ASM payment year" as a calendar year in which CMS applies the ASM payment multiplier to Medicare Part B payments based on the final score achieved by that ASM participant for the ASM performance year 2 years prior.

In the 2026 PFS proposed rule (90 FR 32561), we proposed that, similar to MIPS, an ASM payment year would occur 2 calendar years following the ASM performance year. We explained that the ASM participant's final score and ASM payment adjustment factor would be determined for an ASM performance year and applied 2 years later in the corresponding ASM payment year. For instance, the CY 2027 ASM performance year would correspond to the CY 2029 ASM payment year. This will allow time for ASM participants to submit required data for each of the ASM performance categories as described in section III.C.2.d of the CY 2026 PFS proposed rule and for CMS to score submitted data for the ASM performance categories, calculate final scores, and determine payment adjustments as discussed in sections III.C.2.d., III.C.2.e, and III.C.2.f of the CY 2026 PFS proposed rule. We stated that the final data submission of measures and activities would occur in CY 2032, with final model payment adjustments in CY 2033. We explained that this timeline aligns with MIPS in that those who report traditional MIPS or MVPs receive an adjustment to their Medicare Part B fee-for-service payments 2 years after the corresponding MIPS performance period based on a total score calculated from reported measures and activities across the MIPS performance categories (see §§ 414.1305, 414.1320, 414.1365, and 414.1405(e)). We stated our belief that 5 ASM performance years followed by 5 ASM payment years

would allow sufficient time for ASM participants to invest in care delivery transformation and for CMS to evaluate the impact of the model's payment adjustments.

TABLE B-D1: ASM PERFORMANCE YEARS AND ASM PAYMENT YEARS

Calendar Year	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031	CY 2032	CY 2033
ASM Performance Year (PY)	X	X	X	X	X		
ASM Participant Data Submission		Report for PY 2027	Report for PY 2028	Report for PY 2029	Report for PY 2030	Report for PY 2031	
Final Score & ASM Payment Adjustment Factor Calculation		Released for PY 2027	Released for PY 2028	Released for PY 2029	Released for PY 2030	Released for PY 2031	
ASM Payment Years			Payment adjusted for PY 2027	Payment adjusted for PY 2028	Payment adjusted for PY 2029	Payment adjusted for PY 2030	Payment adjusted for PY 2031

We believe that an ASM test period of 7 years, as opposed to a shorter duration, is necessary to obtain sufficient data to compute a reliable impact estimate and determine the next steps regarding potential expansion or extension of the model. Further, we believe that a test period of 7 years is necessary to address and mitigate any potential implementation issues or unintended consequences. For a discussion of ASM's evaluation approach, please see section III.C.2.l of this final rule.

In the CY 2026 PFS proposed rule (90 FR 32562), we proposed an ASM start date of January 1, 2027. We also considered proposing an earlier January 1, 2026 ASM start date, but, given the rulemaking process, we believe an earlier start date would not give ASM participants enough time to prepare for participation.

We invited public comments on the proposal at § 512.705 to define the "ASM test period" as the 7-year period from January 1, 2027 to December 31, 2033, "ASM performance year" as a 12-month period beginning on January 1 and ending on December 31 of each year during the first 5 calendar years of the ASM test period, and "ASM payment year" as a calendar year in which CMS applies the ASM payment multiplier to Medicare Part B payments based on the final score achieved by that ASM participant for the ASM performance year 2 years prior. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed test period of the model, noting that the length of time is an adequate period for participation and CMS data collection.

Response: We appreciate the commenter for their support.

Comment: A few commenters did not support the proposed 2-year gap between the ASM performance year and ASM payment year. The commenters recommended that the ASM payment be as close to real-time as possible, noting that reducing the gap would enhance the relevance of ASM to specialists, create a more effective incentive structure, and provide clinicians with the ability to reinvest in practice transformation, especially for small practices.

Response: While we understand the value in real-time data, ASM participants must be allowed ample time to submit the required data for each of the ASM performance categories. We are adopting a single data submission period to minimize burden for ASM participants and data submission will occur during the calendar year following the ASM performance year. Following data submission, we will need time to generate final scores and determine payment adjustments. Similar to MIPS, we believe EBCMs are the most appropriate and objective criteria by which to assess cost performance. Because EBCMs are constructed at the completion of each calendar year, the data will only become available in the year following the ASM performance year, at which time we will determine scores and payment adjustments. As the adjustments are applied on an annual basis, the soonest we could apply those ASM payment adjustments will be in the following calendar year. This policy is similar to MIPS in that Medicare Part B fee-for-service payment adjustments occur 2 years after the corresponding MIPS performance period. For these reasons, we are finalizing the "ASM performance year" and "ASM payment year" definitions as proposed. As we discuss in section III.C.2.j of this final rule, we intend to share data and provide data feedback with ASM participants during an ASM performance year to help participants better understand their potential performance.

Comment: A commenter supported the proposed start date of ASM on January 1, 2027, stating it allowed a satisfactory lead time for ASM participants. Another commenter supported January 1, 2027 as a reporting-only year with no incentives or penalties to allow clinicians time to build a baseline understanding of the model. Another commenter suggested CMS to release specific model requirements as soon as possible to help clinicians prepare for ASM implementation.

Several commenters indicated that additional time is needed for CMS to analyze MVP performance data to further inform model development, identify potential methodological flaws, and

engage with interested parties. Many commenters recommended a delayed start date to ensure readiness and minimize technical and administrative disruptions to clinicians who will be required to build infrastructure to train staff, support clinical workflows, and submit data using eCQMs. Several commenters indicated that additional time is needed for third-party vendors to prepare for reporting requirements, such as developing and testing eCQM collection types for each required measure to allow full electronic submissions. A commenter called attention to the requirements for the improvement activities performance category and the care coordination that will be required. The commenter noted that if a final list of participants is not released until the middle of 2026, a start date of January 1, 2027 could create a burden for clinicians required to participate.

The commenters stated that the complexity of these tasks, especially for organizations with multiple reporting entities and systems, makes a 2027 deadline unrealistic for successful implementation. A few commenters stated that ASM should first be instituted as a pilot test. Another commenter stated implementation should be delayed allowing for comprehensive testing with appropriate safeguards and engagement with interested parties, particularly with rural providers and heart failure specialists. Another commenter stated that, because ASM directly targets clinicians who are deeply integrated into the established MIPS and MVP frameworks, ASM will be like a mandatory replacement for their current reporting structure, as such the more accelerated timelines adopted for other recent Innovation Center models, such as the Increasing Organ Transplant Access (IOTA) and Guiding an Improved Dementia Experience (GUIDE) models are less appropriate for ASM.

A commenter stated health IT vendors need adequate lead time to program, test, and deploy the necessary software solutions for data capture and submission. The commenter stated that because participant eligibility and lookup tools will require significant time to develop and stabilize, CMS should take additional time to conduct a robust, multi-year educational campaign to ensure clinicians and their support staff fully understand eligibility, data collection requirements, and the scoring methodology. The commenter suggested a 2028 or 2029 start date would allow time to finalize all rules and the technical infrastructure for data submission for ASM.

Response: We acknowledge the commenters' concerns regarding the time needed to prepare for ASM implementation. We introduced the model in the CY 2026 PFS rulemaking cycle, rather than the

CY 2027 rulemaking cycle, to give clinicians an additional year to prepare for implementation. In addition, for the first year of the model, we will notify preliminarily eligible clinicians of their expected selection for the model to provide additional time to prepare and anticipate operational updates. We note that many of the clinicians that will be eligible for ASM are already familiar with MIPS reporting or have experience with other alternative payment models and have processes in place that can be used to meet ASM data submission requirements.

With respect to a pilot test of ASM, we note that ASM is itself a model test and disagree that it needs to be piloted before implementation. We developed the model after learning from previous Innovation Center models and MIPS, public comments to the 2024 Request for Information (RFI) (89 FR 61596),[166] and extensive input from provider groups, health systems, academics, and other interested parties. We agree with the commenter that ASM is purposely directed at clinicians who are already familiar with the MIPS framework. ASM is in part a direct response to input from interested parties regarding the need for more targeted cohorts and peer-to-peer comparisons. We believe ASM will provide valuable, pertinent, and actionable feedback to clinicians who have previously doubted the relevance of their performance scores.

With respect to the time needed to update technical requirements to meet the reporting requirements of the model, we note that we plan to use the Quality Payment Program portal to reduce disruptions to current reporting processes.

Comment: A commenter stated that the proposed launch of ASM represents a departure from the established and historically successful precedent of a phased-in approach to transition clinicians to new models. A few commenters suggested a staged approach to ASM implementation would mitigate risk and ensure readiness. A commenter suggested allowing MVPs to become the primary quality reporting program for most specialists following the planned sunset of traditional MIPS. They suggested that launching ASM as a voluntary alternative to MVPs for eligible clinicians in its first 2 years to allow clinicians, vendors, and CMS to test the model in a real-world environment, gather crucial data, and resolve operational issues without penalizing unprepared participants.

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[166] Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Medicare Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments.

Response: We acknowledge that we have previously staged implementation of model requirements when such an on-ramp was warranted. However, as value-based payment models have become more common, more providers have established processes in place that can be leveraged to meet ASM requirements. Therefore, ASM may not require entirely novel operational processes for all ASM participants, and we believe the advanced notice described in the CY 2026 PFS proposed rule is sufficient. We do not believe an alternative timeline for transitioning from MIPS to ASM is necessary as we did not propose a full-scale transition from MIPS or MVPs. As stated in the CY 2026 PFS proposed rule (90 FR 32593), we believe ASM can potentially inform updates to the Quality Payment Program and the MVP reporting option. While many participants who are assigned the specific specialty codes we have selected for ASM may shift between MIPS and ASM, depending on whether they meet the ASM eligibility criteria for a given year, ASM is only testing a small subset of provider types for the ASM heart failure and low back pain cohorts. That is, the majority of MIPS providers will not be eligible for ASM and will continue to report through MIPS throughout the ASM test period. As an Innovation Center model test, ASM will require evaluation and would need to meet the requirements for Innovation Center model certification to be expanded.

After consideration of public comments, we are finalizing our proposed definitions for "ASM test period" and "ASM payment year" as proposed at § 512.705. We are also finalizing January 1, 2027 as the ASM start date as proposed. We did not receive any comments related to our proposed "ASM performance year" definition and are, therefore, finalizing as proposed at § 512.705.

c. ASM Participants

(1) Mandatory Participation

In the CY 2026 PFS proposed rule (90 FR 32562 through 32563), we discussed our belief that requiring clinicians to participate in the model test is necessary to eliminate selection bias, yield generalizable results, and ensure an evaluable comparison group. Voluntary participation in Innovation Center models has demonstrated that those electing to voluntarily participate are more likely to have the infrastructure and experience to succeed under the model. Moreover, in a voluntary model, when the opportunity for financial gain is reduced or uncertain, participant attrition increases. We believe requiring participation in ASM would prevent this type of selection bias.

We stated that mandatory participation in ASM would also ensure a sufficient volume of participants to produce a diverse, representative evaluation of clinicians providing specialty care to Medicare beneficiaries with heart failure and low back pain. We believe ASM could highlight inefficient care utilization patterns and potentially inform quality improvement and care coordination incentives for application in the Quality Payment Program and future Innovation Center models. Finally, we stated mandatory participation is necessary to generate a statistically robust test of ASM with results that are reliable, generalizable, and able to support potential model expansion.

Therefore, we proposed at § 512.710(a)(1) that participation in ASM would be mandatory for all clinicians who meet the ASM participant eligibility criteria at § 512.710(b) and for any year that an ASM participant meets the ASM eligibility criteria, they would subject to the ASM requirements. Specifically, the ASM participant would be required to submit data in accordance with § 512.720, would be assessed in accordance with § 512.715, would be scored in accordance with § 512.745, and would receive an ASM payment adjustment in accordance with § 512.750. In addition, for any such year, the ASM participant would be eligible for any waivers described in section III.C.2.h. of this final rule. We also proposed that once a clinician meets the ASM participant eligibility criteria, they would be considered an ASM participant for the duration of the model. We also proposed that clinicians would be exempt from MIPS reporting for any ASM performance year that they meet ASM participant eligibility criteria.

We proposed at § 512.710(a)(2) that for any subsequent ASM performance year that a previously selected ASM participant does not continue to meet the ASM participant eligibility criteria, the ASM participant would not be subject to the ASM requirements. Specifically, the ASM participant would not be required to submit data in accordance with § 512.720, would not be assessed in accordance with § 512.715, would not be scored in accordance with § 512.745, and would not receive an ASM payment adjustment in accordance with § 512.750. In addition, for any such year, the ASM participant would not be eligible for any waivers described in section III.C.2.h. of this final rule. Because the Medicare waiver at § 512.775 only waives the requirements of section 1848(q) of the Act, and its implementing regulations for an ASM performance year that an ASM participant meets the ASM participant eligibility criteria, the ASM participant would be subject to any MIPS reporting obligations, if applicable, and would receive a MIPS payment adjustment 2 years later, in accordance with current regulations for any performance year

that they do not meet the ASM participant eligibility criteria. Because ASM participants may be subject to MIPS for any ASM performance year that they do not meet the ASM participant eligibility criteria, ASM payment adjustments may be applied during an ASM payment year during which an ASM participant is not actively participating in ASM and is instead participating in MIPS.

Specifically, we proposed for the--

● 2027 ASM performance year: ASM participants would be measured for performance and exempted from MIPS participation, if applicable, during CY 2027; report and be scored during CY 2028; and receive payment adjustments for CY 2027 performance in CY 2029;

● 2028 performance year: ASM participants meeting ASM participant eligibility criteria for the 2028 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2028; report and be scored during CY 2029; and receive payment adjustments for CY 2028 performance in CY 2030;

● 2029 ASM performance year: ASM participants meeting ASM participant eligibility criteria for the 2029 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2029; report and be scored during CY 2030; and receive payment adjustments for CY 2029 performance in CY 2031;

● 2030 ASM performance year: ASM participants meeting ASM participant eligibility criteria for the 2030 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2030; report and be scored during CY 2031; and receive payment adjustments for CY 2030 performance in CY 2032; and

● 2031 ASM performance year: ASM participants meeting ASM participant eligibility criteria for the 2031 performance year would be measured for performance and exempted from MIPS participation, if applicable, during CY 2031; report and be scored during CY 2032; and receive payment adjustments for CY 2031 performance in CY 2033.

We solicited public comments on our proposals at § 512.710(a) to require mandatory participation in ASM, to consider ASM participants as ASM participants for the duration of the model, and to exempt ASM participants from reporting under MIPS for only those years that they meet ASM participant eligibility criteria. The following is a summary of the comments we received and our response.

Comment: Several commenters supported ASM as a mandatory model, noting that it would increase transparency, participation, and competition; minimize selection bias in terms of who participates and which measures are reported; and improve outcomes, reduce costs and low value care, and transform care delivery. A few commenters shared their belief that mandatory participation is necessary for ASM to gain the critical mass of participating clinicians required for robust data collection and improve the generalizability of model findings. A commenter noted that the low voluntary adoption rates of programs and reporting options, such as MVPs, suggest that mandatory participation is necessary for full adoption.

Response: We appreciate commenters for their support of ASM as a mandatory model.

Comment: Many commenters did not support mandatory participation for ASM, noting their belief that the model could impose significant financial risks and administrative burdens which are inappropriate since this is a new, untested performance framework that still has measures in development. A commenter recommended excluding clinicians who specialize in heart failure from mandatory ASM participation in the model. Another commenter recommended that CMS develop an optional track for physicians who treat potential conditions of focus. Many commenters shared concerns that mandatory ASM participation may destabilize practices, increase practice consolidation, and reduce patient access to community-based specialty care. They believe this is a particular risk for the rural, solo, and small practices, without the bandwidth for successful participation. They stated that vulnerable rural communities would not be able to overcome the administrative burden of ASM, potentially triggering hospital closures or result in physicians, such as cardiologists, dropping participation in Medicare altogether. Another commenter generally supported integrating rural clinicians into value-based care models but recommended that CMS allow an opt-out option for rural clinicians, if needed, because of additional burden related to a lack of bandwidth or readiness to participate. Another commenter shared a concern that mandatory participation may not uphold the statutory intent of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). A few commenters raised concerns about overlapping reporting and payment programs. Another commenter stated that a mandatory model with two-sided financial risk would require expensive technology investments. Many commenters recommended ASM participation incentives paired with voluntary participation to build trust between CMS and clinicians, ease administrative burdens, and allow time for adaptation. Another commenter recommended allowing

ASM participants to opt-out of the model if their patient population within a cohort declined significantly since the attribution year.

Response: We acknowledge these comments but believe that the language in Section 1115A(d)(2) of the Act gives the Innovation Center the authority to implement and test ASM. Specifically, we believe that the preclusion of administrative or judicial review of the specific policies was intended to ensure our ability to implement mandatory models. We proposed ASM as a mandatory model because allowing voluntary participation would likely result in only high performers joining the model, rather than incentivizing all clinicians to improve care. As previously stated in this section of the final rule, we believe that requiring clinicians to participate in the model test is necessary to eliminate selection bias, yield generalizable results, and ensure an evaluable comparison group. Allowing clinicians to opt-out of ASM would undermine the model test given concerns about selection bias. We note that if an ASM participant has a significant decline in patient population and does not meet the required case minimums for quality or cost measures during ASM performance year, described in sections III.C.2.d.(2).(h) and III.C.2.d.(3).(f) of this final rule, they would not generate a performance score or receive a subsequent payment adjustment. We believe this is a fair approach to preventing undue penalties due to unexpectedly lower case volumes. We refer readers to further discussion on this provision in section III.C.2.e.(2).(b) of this final rule.

Including participants in rural areas is necessary to evaluate the impacts of the model were it to be expanded to rural areas. We note that CBSAs with a low volume of eligible episodes (that is, CBSAs with no eligible clinicians with at least 20 episodes in the reference year), which includes some rural areas, would be excluded from the model. Additionally, rural areas not assigned to a CBSA would be excluded. For a full discussion on the selection of mandatory geographic areas, please see section III.C.2.c.(4) of this final rule.

We previously noted that many of the clinicians that will be eligible for ASM, including those in rural areas, are experienced with other value-based payment models and have processes in place that can be used to meet ASM data submission requirements. In addition, ASM reporting can be done through the established MIPS portal to minimize disruptions to current reporting processes and reduce additional costs to providers. We do not anticipate that ASM participants will need to make significant technological

investments to meet the reporting requirements of the model. We refer readers to sections III.C.2.d.(2)(b) and III.C.2.d.(2)(c) of this rule for a discussion of the finalized quality measure sets for the ASM heart failure and ASM low back pain cohorts. We also refer readers to section III.C.2.c.(4) of this rule where we discuss the model geography, including rural mandatory geographic areas.

Comment: A few commenters did not support the proposal requiring clinicians, once selected for ASM, to remain ASM participants for the entire duration of the model. A few commenters requested clarification on the proposed requirement that clinicians who meet ASM participant eligibility criteria for an ASM performance year would be considered an ASM participant for the remainder of the model. The commenters believed there was a discrepancy between the policy that clinicians who are ASM participants will remain participants for the duration of the model at § 512.710(a)(1) and the proposed policy to reassess ASM participant eligibility each performance year and exclude clinicians who no longer meet the eligibility criteria for the upcoming ASM performance or payment year, making them eligible for MIPS. Another commenter requested clarity on MIPS exemptions if an ASM participant does not meet ASM eligibility criteria during a performance period

Response: We are happy to provide further clarification regarding ASM participation. An ASM participant is any clinician who meets the ASM participant eligibility criteria for any ASM performance year. Once a clinician meets the ASM participant eligibility criteria for a given year, the clinician will remain an ASM participant for the remaining years of the model. We defined ASM participants this way because ASM participants will be considered ASM participants when submitting ASM data and receiving ASM payment adjustments during non-performance years.

The first ASM performance year that a clinician is selected as an ASM participant, the clinician would be required to meet ASM requirements and would be exempt from MIPS reporting requirements, if applicable. However, all ASM participants will be reassessed on an annual basis to determine whether they still meet the ASM participant eligibility criteria for each subsequent ASM performance year. Any subsequent year that an ASM participant meets the ASM participant eligibility criteria, the ASM participant must meet ASM model requirements, and is exempt from MIPS reporting requirements, if applicable. If an ASM participant does not meet the ASM participant eligibility criteria for a subsequent ASM performance year, they will remain an ASM participant but will not be required to meet ASM

requirements for the applicable ASM performance year. For example, if a cardiologist meets the ASM participant eligibility criteria for the CY 2027 ASM performance year, that cardiologist is an ASM participant for the duration of the model. The cardiologist would be required to meet the ASM reporting requirements during CY 2027 and would be exempted from MIPS participation, if applicable, during CY 2027. However, when reassessed the following year, if the cardiologist does not meet the ASM participant eligibility criteria for the CY 2028 ASM performance year, while still considered an ASM participant, the cardiologist will not be required to meet ASM requirements in CY 2028 and will be required to report under MIPS in CY 2028, if applicable. The cardiologist would then be reassessed for the CY 2029 ASM performance year, and if they meet the ASM participant eligibility criteria for the CY 2029 ASM performance year, the cardiologist will be required to meet the ASM reporting requirements during CY 2029 and will be exempted from MIPS participation, if applicable, during CY 2029. (For information on the ASM participant notification process, please see section III.C.2.c.(5) of this final rule.)

Comment: A commenter suggested a defined process for clinicians to correct their ASM participation status. Another commenter noted that allowing a clinician to correct their participation status would help address potential discrepancies arising from administrative data or misalignment between PECOS specialty information and actual clinical practice.

Response: We appreciate the commenters' concerns. We note that ASM will not assign specialties to clinicians directly. Rather, we will rely on the specialty code assigned to a clinician's Medicare Part B claims, which is based on PECOS information provided by clinicians themselves, or, in the case that a clinician has listed more than one primary specialty in PECOS, the specialty assigned most frequently to their Part B claims. As we will be unable to correct ASM participation status, to avoid potential errors, clinicians should confirm and provide necessary updates to their PECOS information if they believe that their current specialty designation does not reflect their actual clinical practice.

Comment: A few commenters supported the proposed exemption of ASM participants from MIPS during the performance periods when they are eligible for ASM, thereby avoiding duplicative work and alleviating provider burden. Another commenter noted that although an ASM participant is exempt from MIPS requirements, ASM measures, scoring policies, and payment adjustments largely mirror those of MIPS.

Response: We appreciate the commenters who support our proposal to exempt ASM participants from MIPS reporting for years that they meet the ASM participant eligibility requirements. We agree with the commenter that ASM mirrors MIPS in many ways. However, ASM will employ a more targeted approach by using the same performance measures to evaluate clinicians furnishing the same services. ASM leverages the existing MVP policies, while deviating from MVP policies in specific ways. To ensure a more analogous comparison between specialists, unlike the voluntary measure and activity selection permitted under the MVP reporting option, ASM will require clinicians to report on a specific set of measures and activities clinically relevant to their specialty type and either heart failure or low back pain. Also, while clinicians reporting under MVPs are scored against the entire pool of MIPS clinicians, ASM will assess performance against only those clinicians treating the same chronic condition.

Comment: A commenter did not support the proposed exemption of ASM participants from participating in MIPS and recommended that CMS allow clinicians the option of reporting in MIPS rather than ASM if only a small portion of their patients are receiving chronic care for heart failure or low back pain. The commenter recommended that clinicians retain the ability to report on different quality measures within MIPS if the clinician believes those measures better reflect the types of services delivered for the majority of the patients they treat.

Response: We believe that the specialties selected for the ASM cohorts are targeted so that they would be unlikely to comprise providers caring for only a small portion of patients with low back pain or heart failure. The EBCM episode volume ASM participant eligibility criterion described in section III.C.2.c.(3)(b) must be met to ensure ASM participants provide a sufficient amount of care for heart failure or low back pain. Additionally, our intention in creating this model is to create like-to-like comparisons between similar providers and avoid the selection of disparate quality measures. This requires participants to report on the same measures related to the same condition. Continuing to allow providers to report on different quality measures would not be different than the current MIPS reporting option and obviates the goals of ASM.

Comment: A few commenters requested clarification on the interplay between MIPS and ASM. A commenter questioned whether group practices can still be submitted at the TIN level for MIPS if the group also has an identified ASM participant and supports ASM group submissions. Another commenter

stated that exempting ASM participants from MIPS creates significant ambiguity regarding impacts for clinicians who are part of larger group reporting structures, such as those submitting under an MVP or as part of the Shared Savings Program reporting the APP measure set. The commenter stated that there are implications for group reporting requirements in other programs with respect to data completeness, and whether removing clinicians from the reporting pool would make it mathematically impossible for that group to meet its own program requirements. The commenter pointed to additional burden if an ASM-eligible clinician is expected to "dually report" for both ASM and an MVP/APP to satisfy Shared Savings Program ACO/APP data completeness obligations. Another commenter requested that CMS establish a clear program hierarchy for ASM participation and other reporting obligations. They also requested whether CMS would adjust the denominator for a group's data completeness calculation in its MVP or APP if ASM participation supersedes all other reporting obligations. Another commenter recommended that ASM participants not include clinicians who were part of a group practice for the QPP submission in CY 2024 or 2025.

Response: We appreciate the comments and will take them into consideration when determining how to address ASM participant overlap with subgroup-level or group-level reporting under MIPS. We will also ensure appropriate guidance is provided prior to model implementation.

After consideration of public comments, we are finalizing without modification our proposal at § 512.710(a) that clinicians who meet the ASM participant eligibility criteria for any year of the model will remain ASM participants for the duration of the model. We are also finalizing our proposal to exempt ASM participants from reporting under MIPS for only those years that they meet ASM participant eligibility criteria as proposed.

(2) ASM Participants

In the CY 2026 PFS proposed rule (90 FR 32563 through 32564), we proposed that only certain clinicians who treat heart failure and low back pain would be required to participate in ASM. We proposed at § 512.705 to define the term “ASM participant” to mean an individual clinician who, for at least one ASM performance year, satisfies the ASM participant eligibility criteria described in section III.C.2.c.(3). of the CY 2026 PFS proposed rule and has been selected for participation in the model as described in section III.C.2.c.(5). of the CY 2026 PFS proposed rule. For ASM specifically, we proposed

to define “clinician” as any “eligible professional” defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination. We proposed to define “ASM heart failure participant” as an ASM participant who meets the ASM participant eligibility criteria related to heart failure and “ASM low back pain participant” as an ASM participant who meets the ASM participant eligibility criteria related to low back pain (discussed later in this section of this final rule). We note that the definition of “model participant” contained in § 512.110 should be interpreted to include each ASM participant. We proposed to define an “ASM targeted chronic condition” as a medical condition that is a core focus of ASM; that is, heart failure or low back pain. We proposed to define an “ASM cohort” as a group of ASM participants who treat the same ASM targeted chronic condition; specifically, we proposed an ASM heart failure cohort and an ASM back pain cohort for this model. We proposed to define the “ASM heart failure cohort” to be composed of all ASM heart failure participants and the “ASM low back pain cohort” to be composed of all ASM low back pain participants. We noted that the proposed ASM cohorts would not include nonphysician practitioners (NPP) because Medicare does not currently assign specialty codes to NPPs. Therefore, NPPs would not meet the ASM participant eligibility criteria proposed at § 512.710(b)(2), which states that only clinicians identified by one of the specialty types at § 512.710(d) may be ASM participants.

We stated in the CY 2026 PFS proposed rule (90 FR 32563) that we also considered defining an ASM participant as a group of clinicians within a single practice, provided each clinician individually meets the ASM participant eligibility criteria. However, including groups of specialists would result in fewer ASM participants overall and add complexity to comparing performance across the ASM performance categories and determining final scores. We also believe a group-based approach to ASM participation may not reflect the variable arrangements of care teams, as clinicians may also work outside the group, across multiple service locations and teams. Under the alternative group-level scenario, we would need to provide the ASM participant with a list of clinicians who individually meet the ASM participant eligibility criteria for an applicable ASM performance year. In this case, each eligible clinician on an ASM participant’s clinician list would be considered a downstream participant in ASM, and the ASM participant would be required to contractually bind all downstream participants to comply with all

laws pertaining to any patient-identifiable data requested from CMS and the terms of any agreement with CMS, as a condition of receiving and maintaining data from the ASM participant.

We also considered whether the ASM participant under the alternative participant identification approach would be permitted to add or remove clinicians during an ASM performance year. We believe the addition of model policies and processes to account for individual clinician changes would increase operational complexity and the administrative burden of ASM participants if defined under this alternative group-based definition.

We solicited comments on our proposed definitions at § 512.705. We also sought comments on adopting an alternative group participation policy and, if so, whether groups should be allowed to add or remove clinicians during a performance year.

The following is a summary of the comments we received on the proposed definitions for "clinician," "ASM targeted chronic condition," "ASM cohort," and "ASM low back pain participant" and our responses. We did not receive comments on the "ASM heart failure participant" definition. Because there was significant overlap between comments received regarding the "ASM heart failure cohort" definition and the proposals related to the ASM heart failure cohort, we have consolidated those comments and responses and included them in the ASM Heart Failure Cohort section at III.C.2.c.(2).(a) of this final rule. Similarly, because there was significant overlap between comments received regarding the "ASM low back pain cohort" definition and the proposals related to the ASM low back pain cohort, we have consolidated those comments and responses and included them in the ASM Low Back Pain Cohort section at III.C.2.c.(2).(b) of this final rule.

Comment: A few commenters supported the proposed definition of "ASM participant" to include only physicians in the model and exclude nonphysician practitioners from ASM. Another commenter supported excluding physical therapists and recommended that CMS explore future iterations of value-based models that allow direct participation by physical therapists in ways that are financially and structurally feasible.

Response: We appreciate the commenters for their support.

Comment: Many commenters did not support the proposed "ASM participant" definition to include only select specialty physicians. They shared their belief that non-physician practitioners and

post-acute care providers should be included in the definition, as they have a role to potentially improve outcomes and reduce costs. Many commenters recommended the "ASM participant" definition be expanded to nurse practitioners, physician assistants, physical therapists, occupational therapists, psychologists, social workers, pharmacists and other health care professionals who should have the ability to participate and receive financial adjustments from inclusions in the program. Another commenter recommended including advanced practice registered nurses because they provide care in underserved rural areas. A few commenters recommended creating a voluntary pathway for participation for NPPs through the secondary or tertiary specialty designations in PECOS. Another commenter recommended including primary care and chiropractic physicians in the "ASM participant" definition. A few commenters also referenced Medicare's existing regulatory authority and specialty codes for advanced practice providers, stating that CMS has the capacity to include these professionals under the model. Another commenter recommended CMS recognize the important role that athletic trainers play in the delivery of specialty care, particularly in musculoskeletal and orthopedic care settings.

Response: We note that the proposed definition for "ASM participant" is an individual clinician who, for at least one ASM performance year, satisfies the ASM participant eligibility criteria and has been selected for participation in the model. We did not receive comments specific to the definition. Comments related to the selected specialties and other ASM participant eligibility criteria are discussed individually in section III.C.2.c.(3) of this final rule. We acknowledge the important role of NPPs, post-acute care providers, and other clinicians and agree that the subset of physicians selected for ASM are not the only provider types who deliver low back pain and heart failure care to Medicare beneficiaries. However, ASM aims to build cohorts of like providers who deliver similar services with a comparable ability to drive care improvements. To ensure appropriate comparison among peers, we are limiting ASM to specific physicians.

Providers who do not bill Medicare Part B claims or are not assigned a Medicare specialty code related to a particular chronic condition are not evaluable and are, therefore, not appropriate candidates for this particular model. Operationally, as described in section III.C.2.c.(3).(a).(iii) of this final rule, we have elected to identify ASM participants based on the medical specialty code assigned to Medicare Part B claims. While physicians may be assigned a specialty code specific to their medical specialty, NPPs

(such as occupational therapists, physician assistants, nurse practitioners, and physical therapists) are assigned a Medicare Part B claim specialty code that denotes provider type. For instance, the Medicare Part B claim specialty code assigned to an occupational therapist is the same, regardless of whether they treat patients with low back pain or traumatic brain injury. In addition, we are not relying on PECOS directly for reasons described in section III.C.2.c.(3).(a).(iii) of this final rule, so would not be able to use secondary or tertiary PECOS specialty designations for NPPs. Therefore, we are only able to identify physicians for ASM.

We do not believe it is appropriate to include chiropractors in the model, as we would be unable to score chiropractors on all of the ASM performance metrics and chiropractic training and treatment modalities are not as comprehensive as for other physicians. For example, chiropractors cannot prescribe all medications or order additional testing, such as imaging. We are also unable to include providers, such as athletic trainers, who are not currently recognized as Medicare Part B providers and do not submit Medicare Part B claims. Through ASM, we aim to incentivize specialists directly to work with PCPs to improve outcomes; therefore, including PCPs as participants is outside the goal of the model.

Comment: A commenter recommended refining the "ASM low back pain participant" definition to a specific diagnosis such as stenosis or lumbar disc herniation and adding specialists to the participant definition based on the diagnosis. A few commenters did not support the proposed definition for "ASM low back pain participant" because attribution of a patient's care in a group practice can often start with non-physician practitioners, primary care physicians, or other specialty physicians not identified in the definition. A few commenters agreed with the specialists identified in the proposed "ASM low back pain participant" definition and recommend CMS consider adding additional specialists who oversee non-procedural interventions. Another commenter recommended adding primary care and post-acute care providers to the definition.

Response: We note that the proposed definition for "ASM low back pain participant" is an ASM participant who meets the ASM participant eligibility criteria related to low back pain. Comments related to the selected specialties and other ASM participant eligibility criteria are discussed individually in section III.C.2.c.(3) of this final rule.

Comment: A few commenters supported the proposed alternative to add a group participation option to ASM because of their belief that ASM participants work in multidisciplinary teams to deliver guideline-directed care and manage patients. They stated that allowing group participation would align incentives across the care team, reduce administrative complexity, broaden patient inclusion and increase data submissions. A commenter believed that team-based care is the only sustainable model for managing chronic conditions and that moving to individual-level assessment adds no value. Another commenter noted that TIN level participation supports smaller practices, increasing the likelihood they can make investments in new staff or programs to drive improvements. Another commenter noted that specialty societies recommend multidisciplinary teams providing care for heart failure patients. A few commenters supported allowing groups the option to add or remove participants from ASM during a performance year because they believed it would ensure accurate reporting and fairness since clinicians often change practices. Another commenter believed not allowing for updates during the performance year would create inequities. Another commenter expressed a belief that clinicians practicing in groups should not be part of any ASM cohorts.

Response: We appreciate comments on the alternative approach of allowing group ASM participants and whether, under this alternative policy, groups should be allowed to add or remove ASM participants during an ASM performance year. We disagree that individual-level assessment adds no value and remind commenters that ASM is partly in response to interested parties requesting more targeted and individual performance feedback. We also believe that individual-level performance assessment can create a strong incentive for performance improvement. We will take these comments into consideration should we propose to include group participants in future years of the model. Any change would be undertaken under a notice and comment rulemaking.

After consideration of public comments, we are finalizing the definitions for "ASM participant" and "ASM low back pain participant" as proposed at § 512.705. We did not receive public comments on the definitions for "clinician," "ASM targeted chronic condition," "ASM cohort," or "ASM heart failure participant" and are, therefore, finalizing the definitions as proposed at § 512.705. For comments and responses related to the "ASM heart failure cohort" and "ASM low back pain cohort" definitions, please

see the ASM Heart Failure Cohort section III.C.2.c.(2).(a) and ASM Low Back Pain Cohort section III.C.2.c.(2).(b) of this final rule, respectively.

(a) ASM Heart Failure Cohort

We proposed at § 512.710(d)(1) to only select clinicians who have been assigned a specialty code of cardiology on the plurality of their Medicare Part B claims for the ASM heart failure cohort, provided they meet all applicable ASM participant eligibility criteria under § 512.710(b) for an ASM performance year. We stated that, although other clinicians may treat heart failure, only cardiologists would be selected to participate in the model. Cardiologists commonly provide care to Medicare beneficiaries with heart failure and are well-positioned to improve outcomes by ensuring patients are optimized on guideline-directed medical therapy. We stated our belief that ASM would incentivize cardiologists to work with a primary care team to engage beneficiaries in addressing the root cause of their illness through lifestyle changes and preventing acute episodes.

In addition to the cardiology specialty code, we also considered including clinicians identified by additional cardiac specialty codes, as Medicare uses distinct specialty codes for subspecialists in cardiac electrophysiology, intensive cardiac rehabilitation, cardiac surgery, interventional cardiology, and advanced heart failure and transplant cardiology. Depending on the etiology of heart failure, a beneficiary could receive care from an interventional cardiologist or cardiac electrophysiologist. However, as proceduralists, these specialists do not commonly participate in the longitudinal management of beneficiaries with heart failure and have limited ongoing interactions with primary care.[167] We also considered including cardiologists who specialize in adult congenital heart disease and advanced heart failure and transplant cardiology because these subspecialists often take over as primary managers of care. However, they do not generally co-manage patients or share responsibilities with primary care. Furthermore, they treat a particularly complex patient population, which makes comparing their performance to other cardiologists difficult. For these reasons, we did not propose to include clinicians with specialty codes other than cardiology as ASM participants.

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[167] Sokos G, Kido K, Panjrath G, et al. Multidisciplinary Care in Heart Failure Services. *J Card Fail*. 2023;29(6):943-958. doi:10.1016/j.cardfail.2023.02.011.

We solicited comments on our proposed definition of "ASM heart failure cohort" at § 512.705 and our proposal at § 512.710(d)(1) to only include in the ASM heart failure cohort clinicians with a cardiology specialty code on the plurality of their Medicare Part B claims. We also sought comments on including additional subspecialist cardiology codes in the ASM heart failure cohort.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed eligibility criteria to include only heart failure clinicians who have used a cardiology specialty code. One supported excluding heart failure subspecialists because they believed that cardiologists may provide the bulk of care for exceptionally complex patients.

Response: We appreciate the comments in support of the proposed eligibility criteria for the ASM heart failure cohort, particularly the use of the cardiology specialty code for those clinicians treating heart failure. We agree that cardiologists are in the best position to co-manage patients and share responsibilities with primary care and the exclusion of cardiology sub-specialists is appropriate given that they are more apt to treat complex patients.

Comment: A few commenters stated that the ASM heart failure cohort comprised only of cardiologists is overly narrow and excludes relevant cardiology subspecialists who provide essential components to heart failure care and clinicians who see sufficient volume of heart failure beneficiaries. They stated that excluding these clinicians from ASM would undermine the clinical validity of performance comparison fairness. Several commenters recommended that more cardiology subspecialties be included in the heart failure cohort. A commenter believed that treating heart failure takes multiple team-based approaches and should include specialties like cardiac surgery, interventional cardiology, allied health providers, post-acute care providers, primary care, and advanced primary care providers who manage heart failure patients longitudinally. Another commenter believed additional specialties should be included in the proposed eligibility criteria because they believed that the released EBCM heart failure data shows that half of patients with heart failure are attributed to other types of physicians and nonphysician providers, including cardiologists with subspecialty designations. Another commenter recommended CMS to reconsider the methodology to ensure that clinicians whose Part B payments are at risk can meaningfully participate in the model.

Response: We acknowledge that the subset of clinicians selected for ASM are not the only provider types who deliver care to Medicare beneficiaries and the important role of other clinicians in the treatment of heart failure. ASM is designed to test whether comparing to clinicians who are furnishing similar services for a specific chronic condition improves our ability to assess performance and provides more pertinent and actionable information to specialists. ASM could broaden the pool of participants treating heart failure in future notice and comment rulemaking if it is determined that patterns of care exhibited by other subspecialty types make for fair comparison on the same set of measures.

Subspecialists such as cardiac surgeons and interventional cardiologists treat particularly complex patient populations that would create challenges for comparing performance, as they primarily function as proceduralists rather than comprehensive care managers. Their interactions with heart failure patients are often limited in scope and to a specific area of technical expertise. This contrasts sharply with general cardiologists who often provide ongoing, comprehensive management of heart failure patients. Allied health providers and post-acute providers represent a diverse group of providers who help patients manage their chronic condition(s). Yet, as they typically work under physician supervision, they may not have the clinical authority to make independent treatment decisions or the ability to assume financial risk for patient outcomes. Although some primary care and advanced primary care providers manage heart failure patients longitudinally, ASM focuses on the role of specialists in the treatment of chronic conditions and coordination with PCPs. It is true that EBCM heart failure data shows many patients with heart failure are attributed to subspecialty types and will, therefore, be excluded from the model. The goal of ASM is not to compare performance of all specialist types who have been attributed patients with heart failure. Rather, the goal is to measure the performance of a subset of those clinicians who are most alike in the pattern of care that they provide so that performance is aptly measured and scored.

Comment: A commenter requested that essential data be presented, analyzed, and supported for determining the composition of the ASM heart failure cohort, with discussion of the rationale for including and excluding clinicians who provide essential care for beneficiaries who require heart failure care.

Response: We appreciate the commenter for the response. We believe that we have provided sufficient rationale for determining the composition of the ASM heart failure cohort both in the CY 2026 PFS proposed rule and in this section in response to comments.

Comment: A commenter requested clarity on what "plurality" means within the context of the proposal at § 512.710(d)(1) to only include in the ASM heart failure cohort clinicians with a cardiology specialty code on the plurality of their Medicare Part B claims.

Response: We appreciate the opportunity to clarify what is meant by plurality. Plurality captures the specialty code applied most frequently to a clinician's claims. Majority refers to the specialty code listed on more than 50 percent of claims. In the case that a clinician has more than one specialty code applied to their Medicare Part B claims, the specialty code applied most often would be the specialty code accepted for the purposes of the ASM participant eligibility criteria.

After consideration of public comments, we are finalizing without modification our proposal at § 512.705 to define the "ASM heart failure cohort" as all ASM heart failure participants. We are also finalizing without modification our proposal at § 512.710(d)(1) to include only clinicians with a cardiology specialty code on the plurality of their Medicare Part B claims in the ASM heart failure cohort.

(b) ASM Low Back Pain Cohort

In the CY 2026 PFS proposed rule (90 FR 32564), we identified several nonsurgical and surgical specialties that commonly manage, treat, and maintain long-term relationships with patients with low back pain in the ambulatory setting. Both nonsurgical and surgical specialists offer meaningful, conservative (that is, less invasive) treatment options.[168] However, some low back pain treatments, including spinal fusion for the treatment of non-complex low back pain, may be contributors to low-value care.[169] For this reason, we believe that it would be prudent for ASM to include the specialists who most commonly perform these procedures.

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[168] Steinmetz A. Back pain treatment: a new perspective. Ther Adv Musculoskelet Dis. 2022 Jul 4;14:1759720X221100293. doi: 10.1177/1759720X221100293. PMID: 35814351; PMCID: PMC9260567.

[169] Buchbinder R, Underwood M, Hartvigsen J, Maher CG. The Lancet Series call to action to reduce low value care for low back pain: an update. Pain. 2020 Sep;161 Suppl 1(1):S57-S64. doi: 10.1097/j.pain.0000000000001869. PMID: 33090740; PMCID: PMC7434211.

While surgical specialists are proceduralists, they are also commonly involved in the longitudinal management of Medicare beneficiaries with low back pain. We stated in the CY 2026 PFS proposed rule that we examined whether ASM would meet its goal of comparing like participants if we elected to include both nonsurgical and surgical specialists in the same ASM cohort.

As discussed in the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we stratified 2023 EBCM data by beneficiaries who underwent surgery on their spine and who had complex low back pain and found that, across all specialty types, more than 80 percent of beneficiaries with episodes for low back pain did not undergo spine surgery (83.8 percent for neurosurgery; 90.8 percent for orthopedic surgery), as demonstrated in Table B-D2.

TABLE B-D2: VOLUME DISTRIBUTION OF LOW BACK PAIN EPISODES BY SPECIALTY TYPES IN CY2023

Surgical Status	Complex Low Back Pain	Anesthesiology	Interventional Pain Management	Neurosurgery	Pain Management	Physical Medicine & Rehabilitation	Orthopedic Surgery
No spine surgery	Yes	68.6%	67.4%	60.0%	67.1%	58.7%	46.9%
No spine surgery	No	27.8%	29.0%	23.8%	29.4%	38.1%	43.9%
Spine surgery	Yes	3.1%	3.1%	13.3%	2.9%	2.5%	6.5%
Spine surgery	No	0.5%	0.6%	3.0%	0.6%	0.8%	2.7%

Because orthopedic surgeons and neurosurgeons primarily treat low back pain non-surgically, we believe it is acceptable to include both surgical and nonsurgical specialists in the ASM low back pain cohort. Moreover, the EBCM episode volume eligibility criteria as described in section III.C.2.c.(3)(b) of this final rule would screen out specialists who are not treating low back pain longitudinally in the outpatient setting.

We proposed at § 512.710(d)(2), for the ASM low back pain cohort, to select clinicians with a specialty type of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, and physical medicine and rehabilitation, provided they meet all applicable ASM participant eligibility criteria for an ASM performance year. We noted that there may be some overlap between pain management, interventional pain management, and anesthesiology. However, we proposed to include all three specialty designations to ensure we include anesthesiologists that have not yet updated

their subspecialty with Medicare and those anesthesiologists treating low back pain without pursuing fellowship training.

Although other clinicians do treat low back pain, we proposed that only those specialists listed would be selected to participate in ASM. We also considered other specialists who could trigger higher volumes of low back pain episodes. For example, chiropractors and physical therapists work closely with both PCPs and specialists to treat low back pain, often providing first-line therapy. However, we believe the proposed specialties are better positioned to direct and be held accountable for the longitudinal management of low back pain that may employ a variety of modalities.

We solicited public comments on our proposal at § 512.710(d)(2) to only include in the ASM low back pain cohort clinicians with a specialty code of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, or physical medicine and rehabilitation on the plurality of their Medicare Part B claims. We also sought comments on including alternative low back pain-related specialty types that were considered for the ASM low back pain cohort.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposed ASM low back pain participant and ASM low back pain cohort definitions. A few commenters supported the specialties included in the ASM low back pain cohort with no need to expand to other specialties and believed that surgical care providers are better positioned to assume full accountability for low back pain episodes. A commenter believed that many orthopedic practices manage chronic musculoskeletal conditions, and it is realistic for specialty surgical practices to be included in the model.

Response: We appreciate the comments in support of the ASM low back pain participant definition and the specialties selected for the ASM low back pain cohort. We appreciate the commenters for agreeing that orthopedic surgeons are appropriate provider types for the ASM low back pain cohort.

Comment: A commenter requested clarification and reasoning for including the proposed identified clinicians within the ASM low back pain cohort while excluding other clinicians who provide essential care for beneficiaries. Another commenter said the collection of specialty types is too broad to be statistically useful because clinicians who are not focused on changing the course of lower back pain

as a specialty focus area would not meaningfully contribute to the goal of improving lower back pain care. A couple of commenters recommended excluding surgeons from ASM. Another commenter stated that chronic low back pain is managed through long-term multidisciplinary approaches rather than surgical interventions. Another commenter recommended excluding neurosurgeons. A couple of commenters suggested CMS work with specialty societies for clinicians who treat spine patients to develop a more appropriate value-based opportunity that focuses on the aspects of care where spine surgeons have more direct control.

A commenter expressed a belief that the "ASM low back pain cohort" definition does not foster team-based management of a patient's care over the trajectory of a condition. A few commenters believed attribution of a patient's care in a group practice can often start with non-physician practitioners, primary care physicians, or other specialty physicians not identified in the definition.

Response: We selected the specialties that commonly manage, treat, and maintain long-term relationships with patients with low back pain in the ambulatory setting for the ASM low back pain cohort. We refer readers to section III.C.2.c.(2).(b) of this final rule for a more comprehensive discussion on the reasoning and justification for selecting the specialties for the ASM low back pain cohort. We disagree with the comment that ASM participants who are not clinically or academically focused on changing the course of lower back pain would not meaningfully contribute to improving lower back pain care. We believe this model would incentivize those providers to do so. We also understand that patient care may be transferred between providers in group practices, particularly when utilizing a team-based approach to care for low back pain patients. However, ASM will only focus on providers who meet the ASM participant eligibility criteria, including those related to the volume of episodes for the low back pain EBCM described in section III.C.2.c.(3).(b) of this rule. Providers who see a patient once and refer them to another provider would be unlikely to meet the criteria for an EBCM episode for that patient, as an EBCM episode is only attributed to a clinician when they bill at least 30 percent of the Part B codes for the episode. We disagree that surgeons, including neurosurgeons, should be excluded from the model for the reasons stated in this section III.C.2.c.(2)(b) of the final rule. Specifically, we believe that it would be prudent for ASM to include the specialists who commonly perform spinal fusions.

Comment: A few commenters recommended CMS define ASM low back pain participant and the

ASM low back pain cohort based on specific lumbar spine diseases and conditions rather than grouping all low back pain together. A commenter recommended refining the definition to a specific diagnosis such as stenosis or lumbar disc herniation and adding specialists to the participant definition based on the diagnosis. A commenter encouraged CMS to include a more common set of procedures and workflows that could be more applicable to specialties and groups.

Response: We acknowledge the recommendation to define ASM low back pain participant and ASM low back pain cohort at the diagnosis-level for a subset of low back pain patients. However, such episodes would not be appropriate for ASM because the conditions covered must have an associated MIPS EBCM. In addition, narrower definitions would reduce the volume of episodes and ASM participants in the model. We believe a broader low back pain category will encourage greater coordination among providers caring for patients with a chronic condition that is both complex and multi-factorial, often with overlapping diagnoses.

We also understand that several clinicians are involved when utilizing a team-based approach to care for low back pain patients. Although MIPS will continue to evaluate groups, where handoffs between providers in the same group are common, ASM will only focus on providers who meet the ASM participant eligibility criteria, including those related to the volume of episodes for the low back pain EBCM described in section III.C.2.c.(3).(b) of this final rule. We remind readers that an EBCM episode is only attributed to a clinician when they bill at least 30 percent of the Part B codes for the episode. Therefore, unless the clinician is sufficiently involved in the care for that episode, they would not be attributed to the episode, and the episode would not count toward the EBCM episode volume eligibility criteria.

Comment: A few commenters recommended CMS include additional specialties for the low back pain cohort. A few commenters did not support limiting the low back pain cohort to specialists, such as neurosurgeons and orthopedic surgeons, and recommended instead adding primary care physicians who manage patients with low back pain. A commenter recommended including primary care physicians because a substantial portion of patients are managed solely by PCPs. Another commenter recommended adding NPPs and believed that ASM should capture the chiropractors, behavioral health providers, physical therapists, occupational therapists, massage therapists, or acupuncturists employed in many

physician practices. Another commenter believed that excluding physical therapists will limit ASM's ability to capture the true drivers of value in low back pain care. A few commenters believed the proposed methodology excludes clinicians who see sufficient volume of low back pain beneficiaries. They stated that, according to data released when the low back pain EBCM was being developed, most Medicare patients with low back pain are treated by chiropractors, physical therapists, and primary care physicians who are not included in the "ASM low back pain cohort" definition. Another commenter suggested CMS to ensure that clinicians whose Part B payments are at risk can meaningfully participate in the model. A commenter stated that additional specialists would increase opportunities to achieve Medicare cost savings while providing a more comprehensive, patient-centered, and longitudinal approach for beneficiaries experiencing low back pain. A commenter recommended that, if CMS were to add additional specialties, CMS should examine whether methodological adjustments are necessary to ensure appropriate comparison groups, especially since certain specialists inherently treat more complex, higher-cost conditions.

Response: We acknowledge the important role of other clinicians in the treatment of low back pain and that the subset of physicians selected for ASM are not the only provider types who deliver care to Medicare beneficiaries. While expanding the cohort to include additional provider types and specialties could increase greater cost savings, we remind commenters that ASM is a model test to determine whether comparing specific providers on similar services improves our ability to assess performance and provide more pertinent and actionable information to specialists. ASM also aims to include providers with a comparable ability to drive care improvements and the operational capacity to meet model requirements. Should ASM evaluations confirm its effectiveness in meeting its goals, broadening the pool of participants could certainly be considered in the future. We agree that if additional specialties were added to the model, we would need to consider whether other methodological adjustments were necessary to ensure appropriate comparison groups. At this time, we are not adding additional specialties or provider types.

Through ASM, we aim to incentivize specialists directly to work with PCPs to improve outcomes; therefore, including PCPs as participants is outside the goal of the model. To ensure appropriate comparison among peers, we are limiting ASM to specific specialists.

We do not believe it is appropriate to include chiropractors in the model, as we would be unable to score chiropractors on all of the ASM performance metrics and chiropractic training and treatment modalities are not as comprehensive. For example, chiropractors cannot prescribe all medications or order additional testing, such as imaging.

Operationally, as described in section III.C.2.c.(3).(a).(iii) of this final rule, we have elected to identify ASM participants based on the medical specialty code assigned to Medicare Part B claims. While physicians may be assigned a specialty code specific to their medical specialty, NPPs are assigned a Medicare Part B claim specialty code that denotes provider type. For instance, the Medicare Part B claim specialty code assigned to a physical therapist is the same, regardless of whether they treat patients with low back pain or traumatic brain injury. Therefore, we are only able to identify physicians for ASM.

Comment: A few commenters believed that anesthesiologists, pain management, and interventional pain management should be excluded because most of the clinicians would be at a significant disadvantage, have a low volume of low back pain patients, do not have control over the costs associated with caring for low back pain patients, and will receive negative payment adjustments. A commenter requested clarification in defining roles when the services fall outside a specialist's control, particularly in the case that an anesthesiologist is providing anesthesia services, where the surgeon has primary control over the episode. They believed that pain management and integrated pain management are tertiary referrals, and these types of specialists do not have control of any of the expenses.

Response: We acknowledge comments regarding the perception that some care decisions may be outside of the control of an ASM participant. In fact, one of the aims of ASM is to increase engagement and communication between specialists and their referral sources, typically PCPs. By including specialists who have historically operated in silos, we hope to incentivize those specialists to work together with referring providers to improve care coordination and outcomes for Medicare beneficiaries with low back pain. We disagree that anesthesiologists, pain management, and interventional pain management should be excluded from the model, as these specialists commonly provide long-term care to beneficiaries and perform non-operative interventions to address low back pain. With respect to anesthesia, the EBCM methodology excludes the anesthesia billing codes commonly used when provided services in tandem with a surgical procedure, so those services would not trigger an episode. While some post-operative pain

management codes are included in the EBCM methodology, we would not expect these services to trigger an episode as an EBCM episode is only attributed to a clinician when they bill at least 30 percent of the Part B codes for the episode. In this case, that episode would likely be attributed to the surgeon.

Comment: Several commenters did not support the proposed alternative to include additional specialists in the low back pain cohort because they believe the types of specialists currently selected align with the model's goals of managing patient's chronic disease. Another commenter did not support the proposed alternative to include a subset of orthopedic surgeons who treat low back pain.

Response: We appreciate the comments received on the alternative low back pain-related specialty types that were considered for the ASM low back pain cohort. Should we determine that additional provider types would be appropriate for inclusion in ASM, changes would be undertaken under a notice and comment rulemaking.

After consideration of public comments, we are finalizing the "ASM low back pain participant" and "ASM low back pain cohort" definitions as proposed at § 512.705. We are also finalizing without modification our proposal at § 512.710(d)(2) to include in the ASM low back pain cohort only clinicians with a specialty code of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, or physical medicine and rehabilitation on the plurality of their Medicare Part B claims.

(3) ASM Participant Eligibility Criteria

As discussed in the CY 2026 PFS proposed rule (90 FR 32564 through 32568), when selecting participants for ASM, we sought to ensure (1) we include a sufficient volume of clinicians treating Medicare beneficiaries for the same clinical condition in the ambulatory setting; (2) there is a reasonable expectation that participants can be measured under the model and held accountable for the care provided to Medicare beneficiaries with heart failure and low back pain; (3) the selected clinicians have the operational capacity to meet the ASM performance requirements described in section III.C.2.d of this final rule; and (4) the model test results will be statistically valid, reliable, and generalizable to the specialty types included in ASM nationwide should the model test be successful and considered for expansion under section 1115A(c) of the Act.

Therefore, we proposed at § 512.705 to define "ASM participant eligibility criteria" as the set of criteria defined at § 512.710(b) that CMS uses to determine whether a clinician is selected to participate in ASM. We proposed at § 512.710(b) that clinicians who meet all of the following ASM participant eligibility criteria would be required to participate in ASM:

- Is a clinician who bills claims under the Medicare Physician Fee Schedule.
- Is identified by TIN/NPI as a selected specialty type.
- Meets the EBCM episode volume threshold applicable to an ASM targeted chronic condition.
- Is located in one of the selected mandatory geographic areas.

At § 512.705, we proposed to define "mandatory geographic area" to mean a core-based statistical area (CBSA) or metropolitan division as defined by the Office of Management and Budget (OMB) and selected by CMS under the terms of § 512.710(f). We noted that the proposed mandatory geographic areas may include rural areas as defined by MIPS at § 414.1305, which is a ZIP code designated as rural by the Health Resources and Services Administration's Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

We noted that, as is the case in MIPS, clinicians practicing in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) who provide services that are billed exclusively under the RHC or FQHC payment methodologies would not be selected to participate in ASM. This is because FQHCs and RHCs receive All-Inclusive Rate (AIR) or Prospective Payment System (PPS) payments and do not submit claims under the Medicare Physician Fee Schedule. However, if these clinicians, separately, provide and bill for services under the Physician Fee Schedule, they would be required to participate in ASM provided they meet the ASM participant eligibility criteria. We also stated that clinicians who provide services at Critical Access Hospitals (CAHs) that are paid under Method I would be required to participate, if they meet the ASM participant eligibility criteria, given that such services are paid under the Medicare PFS. Further, we stated that clinicians who provide services at CAHs that are paid under Method II, and meet all ASM participant eligibility criteria, would only be required to participate in ASM if they have not reassigned their billing rights to the Method II CAH; that is, if the clinician continues to submit professional claims through the PFS. This is because when a clinician reassigns their billing rights to a Method II CAH, the CAH bills those services through institutional

claims. As stated in the CY 2026 PFS proposed rule, MIPS uses both professional and institutional claims to trigger EBCMs and include clinicians who have reassigned their billing rights to a Method II CAH. However, in contrast to MIPS, ASM would only use professional claims to trigger EBCMs, and, therefore, would not capture claims for clinicians who have reassigned their billing rights to a Method II CAH.

We sought comments on our proposed "ASM participant eligibility criteria" and "mandatory geographic area" definitions at § 512.705. We also solicited comments on the proposed ASM participant eligibility criteria at § 512.710(b). Specifically, we solicited comments on the proposals at § 512.710(b)(1) that the clinician must bill claims under the Medicare Physician Fee Schedule; at § 512.710(b)(2) that the clinician would be identified by TIN/NPI as a selected specialty type; at § 512.710(b)(3) that the clinician must meet the EBCM episode volume threshold applicable to an ASM targeted chronic condition; and at § 512.710(b)(4) the clinician must be located in one of the selected mandatory geographic areas.

The following is the public comment we received on the "ASM participant eligibility criteria" definition and our response We did not receive comments on the "mandatory geographic area" definition or the criteria at 512.710(b)(1) that the clinician must bill claims under the Medicare Physician Fee Schedule. The remaining ASM participant eligibility criteria proposed at § 512.710(b)(2), § 512.710(b)(3), and § 512.710(b)(4) are discussed in sections III.C.2.c.(3)(a), III.C.2.c.(3)(b), and III.C.2.c.(4) of this final rule, respectively.

Comment: A commenter supported the "ASM participant eligibility criteria" definition since they believed the criteria to be clear.

Response: We appreciate the commenter for their support of the "ASM participant eligibility criteria" definition.

We are finalizing the "ASM participant eligibility criteria" and "mandatory geographic area" definitions as proposed at § 512.705. We are also finalizing the ASM participant eligibility criteria at § 512.710(b)(1) that the clinician must bill claims under the Medicare Physician Fee Schedule as proposed. The remaining ASM participant eligibility criteria proposed at § 512.710(b)(2),

§ 512.710(b)(3), and § 512.710(b)(4) are discussed in sections III.C.2.c.(3)(a), III.C.2.c.(3)(b), and III.C.2.c.(4) of this final rule, respectively.

(a) ASM Participant and Specialty Type Identification

As discussed in section III.C.2.c.(2) of this final rule, we proposed at § 512.710(d) that only a certain subset of clinicians who treat heart failure and low back pain would be required to participate in this model. To identify ASM participants, we proposed to align the Quality Payment Program policies for identifying clinicians and clinical specialty. Specifically, we proposed at § 512.710(b)(2) that the clinician would be identified by TIN/NPI as a selected specialty type.

(i) ASM Participant Identification

As discussed in the CY 2026 PFS proposed rule, Medicare claims are processed using TINs, which may represent an individual clinician or may represent a hospital or group practice. Because we proposed that ASM would evaluate performance at an individual clinician level (TIN/NPI), TIN alone would not be useful for ASM. Individual providers are, however, identifiable by their unique NPI. We stated that when TIN and NPI are used together, CMS is able to identify and evaluate individual providers. NPI-level participation also aligns with the Innovation Center's goal of creating a level playing field for all clinicians and removing unequal benefits afforded to consolidated group practices and health systems.

We noted that the Quality Payment Program identifies MIPS eligible clinicians for the individual participation option, defined at § 414.1305, by a combination of TIN and NPI, (hereafter TIN/NPI) and stated our belief this method is also the best method of identifying clinicians in ASM.

Using TIN/NPI for identifying ASM participants would offer several advantages. First, direct comparison of specialist performance between similar clinicians is a central feature of ASM. Participation at the TIN/NPI level puts the specialist as the unit of comparison, allowing for more meaningful assessment among peers. We stated that this level of participation would also produce more granular performance analysis and useful feedback for clinicians. Second, we also proposed to use TIN/NPI to determine whether clinicians meet the other ASM participant eligibility criteria. Specifically, we proposed to use TIN/NPI to ensure that each ASM participant has met the episode volume criteria for the EBCMs and for assigning clinicians to mandatory geographic areas described later in this section of this final rule.

This approach would maintain consistency between participant identification and performance assessment within ASM and mirrors the methodology used in the Quality Payment Program. Finally, identifying ASM participants at the TIN/NPI level would enable us to identify claims for a single provider who works at more than one location or organization and, therefore, bills under multiple TINs.

We stated our belief that identifying ASM participants at the TIN/NPI level drives direct accountability so that outcomes are clearly attributed to ASM participants. Identifying ASM participants at the TIN/NPI level will allow for like-to-like performance assessment of clinicians who meet ASM participant eligibility criteria. We believe this performance comparison approach will provide granular and actionable insights into best practices and specialty care delivery.

As discussed in the CY 2026 PFS proposed rule, we recognize that an individual clinician may assign their billing rights to multiple TINs (that is, practice across multiple TINs). Such an arrangement will have implications on how we identify ASM participants. For example, if a clinician's NPI is associated with two TINs and meets the ASM participant eligibility criteria for both TINs, then we would consider each TIN/NPI combination to be a separate ASM participant that must separately meet model requirements and report required data. Accordingly, we stated we would separately assess performance and determine payment adjustments for each unique TIN/NPI combination, as described in sections III.C.2.d.(1)(b) and III.C.2.f. of this final rule. We stated that if an NPI is associated with two TINs but only meets the ASM participant eligibility criteria for one TIN/NPI combination, the clinician would only be considered an ASM participant under that one TIN/NPI combination.

We also considered selecting a single TIN/NPI combination to be the ASM participant in the case that a clinician meets ASM eligibility requirements under more than one TIN/NPI combination. Under that scenario, we would have selected the TIN/NPI combination with the majority of EBCM-triggered episodes for a given ASM cohort (see section III.C.2.c.(3)(b) of this final rule for further discussion on EBCM as part of the ASM participant eligibility criteria). However, this alternative could adversely affect participant volume and exclude appropriate beneficiary episodes.

We solicited public comment on our proposal at § 512.710(b)(2) to identify ASM participants at the TIN/NPI level. We also sought comments on the alternative method of using TIN-level specialty type for identifying ASM participants, as well as selecting a single TIN/NPI combination as an ASM

participant in the case that a clinician meets ASM eligibility requirements under more than one TIN/NPI combination.

The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support requiring an individual clinician to participate in ASM separately under all applicable TIN/NPI combinations. They stated that clinicians who assign billing rights to multiple TINs should not be treated as separate participation entities who must meet reporting requirements for each applicable TIN/NPI combination.

Response: Identifying ASM participants at the TIN/NPI level will enable us to identify claims for a single provider who works at more than one location or organization and, therefore, bills under multiple TINs. We believe identifying ASM participants at the TIN/NPI level will drive direct accountability for outcomes that are clearly attributed to each setting in which an ASM participant practices. We note that an ASM participant would only be held accountable for the care they provide under the TIN/NPIs that meet the ASM participant eligibility criteria. Based on our internal analysis performed to inform this policy, we expect this to be a rare occurrence. Moreover, the proposed approach aligns with the ASM performance assessment policies and mirrors the methodology used in the Quality Payment Program. For comments and responses related to data submission for ASM participants who bill under multiple TINs, please see section III.C.2.d.(1) of this final rule.

Comment: A commenter supported the proposed policy to allow ASM participants affiliated with multiple TINs to determine which TIN/NPI combination would be reported to the model.

Response: We appreciate the comment on the alternative method considered for selecting a single TIN/NPI combination as an ASM participant in the case that a clinician meets ASM eligibility requirements under more than one TIN/NPI combination. To clarify, this alternative was not related to reporting but identifying clinicians for participation in ASM. We will take this comment into consideration if we propose changes to the policy in future years of the model.

After consideration of public comments, we are finalizing without modification our proposal at § 512.710(b)(2) to identify ASM participants at the TIN/NPI level.

(ii) Participant Exclusion due to Change in TIN During an ASM Performance Year

In the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we recognized that ASM participants may change practices (as reflected by a change in TIN) during an ASM performance year. In such circumstances, we stated that we would need to determine whether the ASM participant must continue to meet model requirements for the original TIN, for the new TIN, or would no longer be required to meet model requirements under either TIN for that ASM performance year. We proposed at § 512.710(c)(1) that an ASM participant who, during an applicable ASM performance year, no longer assigns their billing rights to the TIN CMS used to identify them as an ASM participant must notify CMS of such change within 30 days of the change in a form and manner determined by CMS. We proposed at § 512.710(c)(2) that an ASM participant who notifies CMS of a change in TIN during an ASM performance year would no longer be required to meet ASM requirements, including data submission requirements described at § 512.720, for the applicable ASM performance year and would instead be subject to MIPS reporting obligations, if applicable. We also proposed that the waivers, including the MIPS waiver established at § 512.775, would no longer apply beginning on the date we determine the clinician is no longer required to meet model requirements for the applicable ASM performance year. We stated that if the ASM participant fails to notify CMS within 30 days of no longer assigning billing rights to the original TIN in the form and manner determined by CMS, then the ASM participant would be required to meet the data submission requirements described at § 512.720 for the applicable ASM performance year.

Given our proposal to determine annually whether clinicians meet ASM participant eligibility criteria for each applicable ASM performance year, we believe that we would naturally identify the movement of individual clinicians to a different TIN between ASM performance years. However, as discussed in the CY 2026 PFS proposed rule, if an ASM participant reassigns their billing rights to a new TIN during an ASM performance year, CMS would not have sufficient data for the new TIN/NPI combination to determine if the ASM participant continues to meet all ASM participant eligibility criteria. For example, we would not have timely EBCM data available for the new TIN/NPI combination to determine if the ASM participant meets the 20 EBCM episode volume criterion (discussed in section III.C.2.c.(3)(b) of this final rule) under the new TIN. Without complete data to evaluate whether the ASM

participant continues to meet the ASM participant eligibility criteria, we proposed, for that ASM performance year, we would not assess the ASM participant in accordance with § 512.715, would not require the ASM participant to submit data in accordance with § 512.720, would not score the ASM participant in accordance with § 512.745, and the ASM participant would not receive an ASM payment adjustment in accordance with § 512.750. Because the proposed Medicare waiver at § 512.775 would only waive the requirements of section 1848(q) of the Act, and its implementing regulations, for an ASM performance year that an ASM participant meets the ASM participant eligibility criteria, we stated that the ASM participant would be required to satisfy any MIPS reporting obligations and would receive a MIPS payment adjustment 2 years later, in accordance with current regulations. In the CY 2026 PFS proposed rule, we stated we intend to monitor TIN changes in each ASM cohort within each ASM performance year and across the ASM model test period. If we determine that changes to this policy are warranted for future ASM performance years, we will propose those changes through notice and comment rulemaking.

We also considered requiring an ASM participant who reassigns their billing rights to a new TIN during an ASM performance year to continue to meet all model requirements for the applicable ASM performance year under the new TIN/NPI combination. As ASM focuses on specialty care related to specific chronic conditions, we considered that the ASM participant would likely continue to furnish services related to ASM targeted chronic conditions under the same specialty type and trigger applicable EBCM episodes during the remainder of the applicable ASM performance year. As discussed in sections III.C.2.d.(3) and III.C.2.e.(2)(b) of this final rule, in the case that an ASM participant under a new TIN/NPI combination does not trigger at least 20 episodes during the remainder of the applicable ASM performance year, the ASM participant would not receive a final score. Accordingly, as we stated in the CY 2026 PFS proposed rule, they would receive no payment adjustments in the corresponding ASM payment year as described at § 512.750(d). However, if an ASM participant under a new TIN were to: (1) receive quality and cost ASM performance category scores discussed in sections III.C.2.d.(2)(i) and III.C.2.d.(3)(g) of this final rule, and (2) meet the requirements to receive a final score as discussed in section III.C.2.e.(2) of this final rule, then we believe it would be appropriate to determine an ASM payment adjustment factor and ASM payment multiplier for the ASM participant under the new TIN/NPI

combination. We ultimately decided to not propose this policy because we believe that conforming to the policy set forth in section III.C.2.c.(1) of this final rule, which requires an ASM participant to satisfy any MIPS reporting obligations when they no longer meet ASM participant eligibility criteria, would avoid adding unnecessary complexity to the model.

We also considered requiring the ASM participant to meet all model requirements under the original TIN/NPI combination for the applicable ASM performance year and, therefore, not requiring the ASM participant to notify CMS of a change in TIN during an ASM performance year. However, we believe that it would be challenging for an ASM participant to access the necessary data to meet the data submission requirements if no longer affiliated with the original TIN. Therefore, we do not believe it would be appropriate to hold an ASM participant accountable for ASM requirements under the original TIN in this situation.

We solicited comments on our proposal at § 512.710(c) to exclude ASM participants who change TIN during an applicable ASM performance year from ASM reporting requirements for that year of the model. We also sought comments on the alternatives of requiring the ASM participant to meet model requirements under their new TIN or under the original TIN/NPI combination that identified them as an ASM participant.

The following is a summary of the comments we received and our responses.

Comment: A commenter agreed with the policy to exclude participants who change TIN during the performance year from ASM requirements. The commenter advised CMS to require participation in the model for subsequent years with their new TIN/NPI combination.

Response: We appreciate the support of our policy to exclude ASM participants who change TIN during an ASM performance year. As discussed in section III.C.2.c.(1) of this rule, ASM participants will be reassessed annually using the ASM participant eligibility criteria to ensure all eligible clinicians are selected for participation in the model.

Comment: A commenter requested clarification on how CMS would handle a change in clinical practice during a measurement year if ASM participant eligibility is decided prior to the measurement year. For example, an anesthesiologist no longer manages low back pain and now only provides anesthesia services in an operating room based on practice decisions.

Response: We understand that, although infrequent, it would be possible for a clinician to change practice settings or service lines based on practice decisions, while remaining under the same TIN. If the ASM participant no longer provides the services that resulted in the provider meeting the ASM participant eligibility criteria, we do not expect they would trigger an adequate number of EBCMs to meet the episode volume criteria to receive a score during the ASM performance year. Therefore, although still an ASM participant, they would not receive a score for that ASM performance year or receive a payment adjustment in the applicable ASM payment year. For a more in-depth discussion on cost ASM performance category scoring, see section III.C.2.d.(3)(g). An ASM participant who changes clinical practice setting during an ASM performance year would be required to notify CMS within 30 days of a change in TIN in a form and manner determined by CMS.

After consideration of public comments, we are finalizing without modification our proposal at § 512.710(c) to exclude ASM participants who change TIN during an applicable ASM performance year from ASM reporting requirements for that year of the model.

(iii) ASM Specialty Identification

In the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we proposed to define "specialty type" as the medical specialty determined by the specialty code indicated on the plurality of a clinician's Medicare Part B claims. We also proposed to identify specialty based on the specialty code indicated on the plurality of a clinician's Medicare Part B claims during the period described in section III.C.2.c.(5) of this final rule to ensure that all clinicians meeting the specialty requirements described at § 512.710(d) are included in the model. Specifically, we proposed to use the same specialty codes used for the Quality Payment Program to identify the specialty of MIPS eligible clinicians as defined at § 414.1305.[170]

As discussed in CY 2026 PFS proposed rule, the specialty codes used on Medicare Part B claims are not reported by clinicians but are assigned to claims by the Medicare Administrative Contractors (MACs) and derived from the clinician-reported specialty designations that are entered in the Provider Enrollment, Chain, and Ownership System (PECOS) as part of the Medicare provider enrollment application. Because a clinician's specialty code could change during an ASM performance year, we

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[170] https://www.federalregister.gov/d/2022-23873/page-70039

proposed to use the specialty code assigned most frequently to a clinician's Medicare Part B claims for determining specialty type for ASM.

We also considered using PECOS specialty designation alone for the purpose of determining specialty type for ASM. However, as discussed in the CY 2026 PFS proposed rule, the PECOS specialty codes are self-reported, and a single clinician may list more than one primary specialty, making it unreliable as a single source for identifying a clinician's primary specialty. We stated in the CY 2023 PFS final rule that given the strong alignment between PECOS data and claims data and our historical use of claims data to identify a clinician's specialty, we believe that Medicare Part B claims data would be the best data source to use to identify a clinician's specialty (87 FR 70039).[171] Moreover, given that the Quality Payment Program uses Medicare claims data, we do not want to create inconsistencies between specialty types for ASM and MIPS. We also considered using the Health Care Provider Taxonomy Codes, which categorize the type, classification, and/or specialization of health care providers. These codes offer more specificity than PECOS (87 FR 70039) and are used when applying for an NPI from the National Plan and Provider Enumeration System (NPPES). However, they are not verified for accuracy.[172] We previously elected not to use the Health Care Provider Taxonomy Codes for MIPS because of uncertainty regarding the reliability of NPPES as a data source for MIPS eligibility determinations (87 FR 70039). We analyzed the congruence between specialty designations made for the purposes of MIPS and those reported in NPPES for the proposed specialty types for both of the ASM targeted chronic conditions. Our analysis found a high degree of congruence between the two specialty type codes, likely because we provide a crosswalk of the Health Care Provider Taxonomy Codes and Medicare Specialty Codes that can be used by a clinician when they enroll in Medicare through PECOS.[173] We stated that given the alignment between these coding systems, we believe that remaining consistent with the specialty type determination methodology used by the Quality Payment Program is important for potential scalability of ASM.

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[171] https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf.
[172] https://data.cms.gov/resources/medicare-provider-and-supplier-taxonomy-crosswalk-methodology.
[173] https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-provider-and-supplier-taxonomy-crosswalk/data.

We solicited comments on our proposal at § 512.710(d) to identify specialty type based on the specialty code indicated on the plurality of a clinician's Medicare Part B claims. We also sought comments on the alternative approach of using PECOS specialty codes alone and Health Care Provider Taxonomy Codes for the purpose of determining specialty type for ASM. The following is a summary of the comments we received and our responses.

Comment: A commenter requested clarification on the use of the term "plurality" in determining specialty identification for mandatory ASM participation. They recommended that CMS provide a quantitative threshold or clear criteria for what constitutes plurality, such as a specific percentage of claims or patient volume because they believe this will ensure transparency and consistency in provider inclusion and reduce ambiguity in compliance. Another commenter recommended CMS identify clinicians who have a relevant specialty type on the majority of their claims instead of a simple plurality. They believe this approach could prevent some clinicians with relatively low procedure volume in the ASM specialties from being included in the model. Another commenter supported using specialty codes on the plurality of Medicare Part B claims to support the proposed specialty type definition. The commenter also recommended that CMS reevaluate this methodology after a period of time and provide detailed reports back to clinicians to help provide insights into why or how clinicians are being included in ASM.

Response: As previously discussed with respect to the ASM heart failure cohort in section III.C.2.c.(2)(a), we believe using plurality is a more appropriate criteria to use for the purpose of identifying ASM participants as it captures the specialty code applied most frequently to a clinician's claims. Using the majority, on the other hand, would imply that a particular specialty code is present on more than 50 percent of claims. In the case that a clinician has more than one specialty code applied to their Medicare Part B claims, the specialty code applied most often would be the specialty code accepted for the purposes of the ASM participant eligibility criteria. Because using the majority would require that a single specialty code be applied to more than half of all Medicare Part B claims, a clinician changing their specialty mid-year may not meet this threshold. Using plurality ensures all clinicians are assigned a specialty for the purposes of the ASM participant eligibility criteria. Using plurality is also aligned with

how specialty is assigned for the purposes of the Quality Payment Program. As with all Innovation Center models, we will perform annual evaluations that will be made public on the ASM website.

Comment: A commenter recommended CMS clarify the source of the clinician's specialty designation assigned by the MACs. Another commenter requested clarification on how ASM will handle clinicians who have multiple specialty codes designated in PECOS. Specifically, they want to know if clinicians would be considered eligible if any of their specialty codes align, or if only their primary specialty code would be considered. Another commenter believed that physicians do not update their specialty designation when starting at new practices and thus the specialty codes can be misleading, especially for multispecialty providers or those working across multiple locations. Another commenter expressed concerns on how CMS would capture specialty designations, noting that many interventional cardiologists are enrolled in Medicare under the designation of cardiology, potentially resulting in inadvertent attribution of heart failure patients. The commenter recommended that CMS review the model to ensure transparency in physician selection and patient attribution. Another commenter recommended allowing specialists to attest to their subspecialty in determining eligibility because Medicare Part B claims do not always accurately reflect the type of care provided and do not reliably identify clinician specialty. Another commenter recommended CMS update PECOS to support the proposed specialty type definition to display specialty codes in addition to specialty description in order to increase transparency and provide guidance on how clinicians with multiple specialties will be handled under ASM eligibility criteria. Another commenter requested clarification on what "specialist" means within the context of low back pain care for ASM.

Response: Clinicians will be assessed for ASM eligibility based on the specialty code applied most frequently to their Medicare Part B claims. We agree with the commenter that clinicians should attest to and ensure that their specialty is correctly entered in PECOS. As discussed in the CY 2026 PFS proposed rule, the specialty codes used on Medicare Part B claims are derived from PECOS. However, we agree with commenters that the PECOS codes alone are unreliable for identifying a clinician's primary specialty. The PECOS specialty codes are self-reported, and a single clinician may list more than one primary specialty or may be delayed in updating their specialty code. In the case that PECOS has more than one primary specialty code listed, the MAC will assign a single specialty code to the claim. As

explained in the Medicare Claims Processing Manual, the MAC assigns the code that corresponds to the greater amount of allowed charges for the previous year.[174] For example, if the TIN/NPI is 50 percent cardiology and 50 percent interventional cardiology, the MAC compares the total allowed charges for cardiology and interventional cardiologist services and assigns the code with the greater amount of allowed charges. We recognize the recommendation that CMS update PECOS, but that is out of the scope of this model. We refer the commenter requesting clarification on what "specialist" means within the context of low back pain to the ASM low back pain cohort section III.C.2.c.(2)(b) of this final rule.

Comment: A few commenters did not support using specialty to include or exclude a physician from being an ASM participant.; the commenters believed that physicians who provide the same type of services to similar patients should not be subject to different payment rules simply because of the specialty code assigned to them. Another commenter believed that participation should be based on the types of patients treated rather than specialty code. Another commenter believed that ASM may inadvertently affect subspecialists who focus on treating other conditions in their practice and recommended adequate notification period for these subspecialities to object to classification and petition for removal.

Response: We disagree that specialty should not be used as one of the eligibility criteria. As explained elsewhere in this final rule, the policies proposed for ASM are, in part, a direct response to previous learnings from the Quality Payment Program and other Innovation Center models, as well as input from interested parties input regarding the need for more targeted cohorts and peer-to-peer comparisons. We have received feedback that in order for quality measurement and performance feedback to be accurate and actionable, clinician performance should be assessed among other clinicians of the same specialty treating similar conditions. We believe focusing on selected specialties will enable us to compare like-to-like care delivery and provide clinicians with more salient data and performance feedback. We agree that ASM should focus on specific types of patients and have, therefore, focused ASM on patients with heart failure and low back pain. We do not expect ASM to affect subspecialists who treat other conditions, as the ASM cohorts only include specific Medicare Part B specialty codes. In

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[174] Medicare Claims Processing, Manual Chapter 26, 10.8.1 Assigning Specialty Codes by A/B MACs (B) and DME MACs. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf

addition, EBCMs will only attribute episodes to clinicians with more than 30 percent of episode spending. We encourage subspecialists to ensure their specialty code in PECOS is accurate and up to date to avoid the need to confirm or object to their specialty classification.

Comment: A commenter suggested CMS to consider supplementing the use of specialty codes in determining the specialty type definition and ASM participation with additional information, such as diagnosis, evaluation and management service mix, patient relationship codes, relevant board certification, etc.

Response: We appreciate the suggestion to supplement specialty codes with other sources of data. While clinicians will be assessed for ASM eligibility based on the specialty code applied most frequently to their Medicare Part B claims, we do rely on clinicians to ensure their specialty is accurate in PECOS. We also note that to account for service mix, MACs rely on the greater amount of allowed charges for the previous year to assign specialty codes to Medicare Part B claims. We stated in the CY 2023 PFS final rule that Medicare Part B claims data would be the best data source to use to identify clinical specialty (87 FR 70039). Moreover, given that the Quality Payment Program uses Medicare claims data, we do not want to create inconsistencies between specialty types for ASM and MIPS.

After consideration of public comments, we are finalizing without modification our proposal at § 512.705 to define "specialty type" as the medical specialty determined by the specialty code indicated on the plurality of a clinician's Medicare Part B claims. We are also finalizing without modification our proposal at § 512.710(d) to identify specialty type based on the specialty code indicated on the plurality of a clinician's Medicare Part B claims.

(b) Episode-based Cost Measure (EBCM) Episode Volume

In the CY 2026 PFS proposed rule, we discussed our belief that the ASM participant eligibility criteria must appropriately identify clinicians who furnish a sufficient volume of services related to ASM targeted chronic conditions and who can be appropriately evaluated on related costs for those conditions. We proposed to identify ASM participants using volume of services related to heart failure and low back pain furnished by clinicians who have a specialty designation that corresponds with the specialty types discussed in III.C.2.c.(2) of the CY 2026 PFS proposed rule (90 FR 32567). We stated that only clinicians with the proposed specialty types who furnish a volume of services above a specific threshold related to

the applicable ASM targeted chronic condition would be identified as ASM participants. That is, not all clinicians who are assigned one of the proposed specialty types related to heart failure or low back pain would be required to participate in ASM.

We proposed to use MIPS EBCMs to determine service volume, rather than assess volume based on claims for individual services. Specifically, we stated that the volume of attributed episodes from EBCMs related to the ASM targeted chronic conditions would serve as the data source by which we evaluate the volume of furnished episodes for ASM. We proposed at § 512.710(b)(3) to use an EBCM episode volume threshold applicable to an ASM targeted chronic condition as an ASM participant eligibility criterion. We proposed at § 512.710(e)(1) to identify ASM heart failure participants using the volume of episodes attributed to a TIN/NPI in accordance with the heart failure EBCM as specified under MIPS. We proposed at § 512.710(e)(2) to identify ASM low back pain participants using the volume of episodes attributed to a TIN/NPI in accordance with the low back pain EBCM as specified under MIPS. We refer readers to section III.C.2.c.(5) of this final rule for a discussion of the processes and specific years of data that we will use to assess EBCM volume to identify ASM participants.

As discussed in the CY 2026 PFS proposed rule, EBCMs assess Medicare resource use for a specific condition or procedure based on only those costs that occur as part of an attributed clinician's care management. CMS uses claims data from Medicare Parts A and B, and some Medicare Part D data, if applicable, to construct the EBCMs (90 FR 32567) . An episode is initiated when a clinician submits a professional claim for at least two separate services, provided to a single beneficiary, that are clinically related to the chronic condition being assessed. Although the episode is initiated and attributed to a particular clinician, the episode includes all Medicare Part A and B services for the length of the episode, as defined by the measure specifications (88 FR 79339 through79347). Therefore, regardless of who provides the care, an episode includes all services related to a beneficiary's condition, routine care services, and consequences of care, and excludes services that are clinically unrelated to the targeted condition of the measure.[175]

As further described in the CY 2026 PFS proposed rule, to attribute episodes to practices and clinicians, CMS first attributes episodes to a TIN when it performs two services indicating care for a

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[175] https://www.cms.gov/files/document/wave-4-measure-development-process-macra.pdf.

particular condition for a single beneficiary within a certain number of days (for example, 180 days); both professional claims must have diagnosis codes for the relevant chronic condition. CMS then attributes episodes to each clinician (NPI) within the group (TIN) that rendered at least 30 percent of the total number of qualifying services during the episode (90 FR 32567). For the heart failure EBCM, CMS also checks that the clinician prescribed at least two condition-related prescriptions on different days to two different patients during the calendar year used to construct the episode plus a 1-year lookback period to ensure that attributed clinicians are actually involved in providing ongoing chronic care management.[176] The low back pain EBCM does not use this additional check since the types of clinicians that manage low back pain may may not prescribe the relevant medication, which could prevent certain clinician types from being attributed episodes.[177]

CMS began development and field testing of the heart failure and low back pain measures in 2022.[178] We finalized the inclusion of the heart failure and low back pain measures to the MIPS cost performance category beginning in the 2024 MIPS performance period/2026 MIPS payment year (88 FR 79319). We also finalized the inclusion of the heart failure EBCM in the Advancing Care for Heart Disease MVP (88 FR 80022 through 80025; 89 FR 99015 through 99019) and the low back pain EBCM in the in the Rehabilitative Support for Musculoskeletal Care MVP (88 FR 80002 through 80007; 89 FR 99050 through 990054).

In the CY 2026 PFS proposed rule, we stated our belief that the construction of the EBCMs and the existing use of these measures within MIPS and MVPs relevant to ASM targeted chronic conditions make the measures an appropriate data source by which to identify ASM participants that furnish enough services and provide longitudinal care management for Medicare beneficiaries diagnosed with ASM targeted chronic conditions (90 FR 32568).

We believe that an annual threshold of 20 or more attributed episodes from an EBCM is appropriate for identifying ASM participants that can be held accountable for quality and cost related to ASM targeted chronic conditions. We have defined a case minimum of 20 episodes for the purposes of scoring chronic condition EBCMs in MIPS, including MVP reporting, as specified in § 414.1350(c)(6)

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[176] https://www.cms.gov/files/zip/2024-cost-measure-information-forms-zip.zip-0.
[177] https://www.cms.gov/files/zip/mips-chrcondition-episode-based-cost-measures-attribution-methodology-2023-zip.zip.
[178] https://www.cms.gov/files/document/wave-4-measure-development-process-macra.pdf.

(88 FR 79346 through 79348). We believe using a similar 20-episode minimum from the calendar year used for determining ASM participant eligibility increases the likelihood that an ASM participant would trigger and be attributed at least 20 episodes within a given ASM performance year. Using a 20-episode threshold would also increase the likelihood that they could be scored on the applicable EBCM during the relevant ASM performance year, as described in section III.C.2.d.(3)(g) of this final rule.

We also considered using an EBCM episode threshold greater than 20 episodes. For example, we considered the effects of using a 30-episode or 50-episode threshold. In our analysis of calendar year 2023 data, we found that a 30-episode threshold would decrease the number of potentially eligible ASM participants by 43 percent for heart failure and 35 percent for low back pain relative to the 20-episode threshold. We found that a 50-episode threshold would decrease the number of potentially eligible ASM participants by 76 percent for heart failure and by 65 percent for low back pain relative to the 20-episode threshold. We believe that the smaller number of potentially eligible ASM participants under a higher EBCM episode threshold would make for a less reliable model test.

We considered but did not propose to add the MIPS low volume threshold of Medicare Part B allowed charges for covered professional services, Medicare patients that receive Medicare Part B covered professional services, and the number of Medicare Part B services provided for individual MIPS eligible clinicians as defined at § 414.1305 as part of the ASM participant eligibility criteria. Adding the MIPS low volume threshold would mean that clinicians would have to meet the MIPS eligibility determinations as defined at § 414.1305, as well as all other ASM participant eligibility criteria, to be identified as an ASM participant. We considered using the same low volume threshold for individual MIPS eligible clinicians given the use of the MVP framework for selecting measures for ASM and to identify ASM participants that furnish a sufficient volume of services related to ASM targeted chronic conditions. Given the importance of using EBCM episode volume to identify ASM participants, we found that inclusion of the MIPS low volume threshold in our ASM participant eligibility criteria would add a secondary service volume criterion. We estimate that the inclusion of the MIPS low volume threshold on top of the EBCM episode volume threshold could potentially decrease the number of ASM participants by more than 50 percent. We believe that the use of the EBCM 20-episode threshold would be a more appropriate criterion for identifying ASM.

We solicited public comments on our proposed ASM participant eligibility criteria at § 512.710(b)(3) stating that the clinician must meet the EBCM episode volume threshold applicable to an ASM targeted chronic condition. We solicited public comments on our proposals at § 512.710(e)(1) to use the heart failure EBCM as specified under MIPS to identify potential ASM heart failure participants and that clinicians who have 20 or more heart failure EBCM episodes attributed to them in accordance with the heart failure EBCM as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year would meet the ASM participant eligibility criterion at § 512.710(b)(3). We solicited public comments on our proposal at § 512.710(e)(2) to use the low back pain EBCM as specified under MIPS to identify potential ASM low back pain participants and clinicians who have 20 or more low back pain EBCM episodes attributed to them in accordance with the low back pain EBCM under MIPS during the calendar year 2 years prior to the applicable ASM performance year would meet the ASM participant eligibility criterion at § 512.710(b)(3). We requested feedback on specifying a higher episode volume threshold and using the MIPS low -volume threshold of Medicare Part B allowed charges for covered professional services for identifying clinicians who provide a sufficient volume of services.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the use of the heart failure EBCM to determine ASM participant eligibility in order to promote consistency between MIPS, MVPs and ASM and align specialist incentives. Another commenter supported the proposal to use low back pain EBCM, noting alignment of specialty incentives with value-based care. A couple of commenters stated that the use of EBCMs has the potential to improve care coordination and reduce unnecessary spending.

Response: We appreciate the commenters for supporting use of EBCMs in the ASM participant eligibility criteria. We agree that it promotes consistency between MIPS and the alignment of specialist incentives. We also agree that the use of EBCMs could help reduce unnecessary spending, and we will include the measure as part of the cost ASM performance category.

Comment: A few commenters expressed concerns with the proposal to use the heart failure and low back pain EBCMs for determining ASM participation, particularly with attribution of the measure to clinicians. A few commenters stated that EBCMs may not attribute the right clinician or may capture

short, high-complexity episodes and hold specialists accountable despite a lack of longitudinal control. Another commenter suggested that CMS add inclusion/exclusion criteria, such as geographic restriction, combination of care patterns or other options to remove episodes that are consultative or tertiary.

Response: We appreciate commenters sharing their concerns on the use of the EBCMs in determining ASM participation. We recognize that episodes based on visits may not pick up all beneficiaries with heart failure or low back pain, but do not agree that the included EBCMs would only capture short, high-complexity episodes. We also disagree that the EBCM episodes would purely be consultative in nature as they require an ongoing care relationship for attribution. We also do not agree that it would be necessary to add exclusion criteria for EBCMs, such as the ones suggested by the commenter. The triggering and confirming codes for the heart failure and low back pain EBCMs focus on care provided by clinicians practicing in non-inpatient hospital settings, so we would not expect to pick up episodes that are primarily tertiary in nature.[179] We remind commenters that the EBCM attribution methodology for the purposes of assessing performance is more complex in its use of triggering and confirming claims than for determining participation. We refer readers to our discussion of the EBCM attribution methodology in section III.C.2.d.(3) of this final rule.

Comment: A commenter expressed concern about using the low back pain EBCM for ASM eligibility, noting the measure is still new and scores have not been released to determine current performance.

Response: The Quality Payment Program began identifying clinicians that provide low back pain services using the low back pain EBCM in the CY 2024 performance period. We believe it is appropriate to similarly include it as an ASM participant eligibility criterion. We do not believe the newness of the measure reduces its effectiveness for ASM participant identification. EBCMs are developed through an extensive process in concert with a panel of clinicians with expertise related to the applicable condition or procedure, including those to whom the measure would be attributed once implemented. More information on the EBCM development process can be found in the annual MIPS Summary of Cost Measures.[180]

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[179] https://qpp.cms.gov/docs/cost_specifications/2025-06-py2025-mif-ebcm-heart-fail.pdf.
[180] https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about

Comment: A commenter expressed concern that the use of EBCMs introduces a complex and potentially burdensome attribution method for an ASM participant to determine which patients would be attributed to an EBCM. The commenter recommended that CMS study the applicability and utilization of patient relationship codes to indicate their level of involvement in the patient's care to factor into patient attribution.

Response: We acknowledge concerns around understanding which patients would be attributed to a particular clinician. We note that the use of EBCMs for determining ASM eligibility would be done retroactively and would simply determine whether a particular clinician saw a sufficient number patients with low back pain or heart failure to be appropriate for inclusion in ASM. The ASM participant eligibility criteria are not reflective of the patients treated by the clinician. We acknowledge the commenter's recommendation to consider patient relationship codes in the ECBM attribution methodology. However, multiple programs and initiatives use the EBCMs and adjustments to the EBCM attribution methodology are out of scope of the ASM provisions. Should we consider incorporating patient relationship codes in the ASM participant eligibility criteria in the future, we would do so through notice and comment rulemaking.

Comment: A couple of commenters supported the proposal for a minimum annual threshold of 20 episodes per EBCM. A commenter stated that EBCMs are specifically designed to assess the conditions of interest and using them to identify participants seems appropriate. The commenter recommended that a case minimum of 20 episodes over 2 years be used, at a minimum, but requested CMS to consider a threshold of 25 to ensure at least one applicable patient per month.

Response: We appreciate the commenters for their support of the proposed 20 EBCM episode threshold in the ASM participant eligibility criteria. We would like to clarify that the 20-episode threshold would be determined within the applicable calendar year used to evaluate clinicians for the ASM participant eligibility criteria. As we discuss in the participant selection and notification process in section III.C.2.c.(5) of this final rule, we will use 2 years of EBCM data to identify the first group of ASM participants for the 2027 ASM performance year. We will use data from CY 2024 to identify preliminarily eligible ASM participants for the 2027 ASM performance year and then confirm their continued eligibility using EBCM data from CY 2025 before the model start. Beginning with the 2028

ASM performance year, we will continue to evaluate eligibility and identify potentially new ASM participants, including NPIs that may change TINs between ASM performance years, using 1 year of EBCM data. y

Comment: Several commenters did not support the proposed minimum annual threshold of 20 episodes for EBCM to identify ASM participants. They stated that the proposed minimum of 20 episodes does not ensure statistical adequacy, particularly with practices with a small caseload. A commenter recommended that CMS consult actuaries and program evaluation experts to determine the appropriate volume cut off. Many commenters expressed concern that the proposed volume of 20 episodes would represent a small subset of the ASM participant patient populations and would put ASM participants at a disproportionate amount of risk for an unrepresentative sample of patients.

Response: We acknowledge the commenters' concerns regarding the 20 EBCM episode volume threshold. However, we disagree that it is an inappropriate volume of cases for determining ASM participant eligibility. A 20 EBCM episode threshold is consistent with the established case volume finalized for scoring of EBCMs in MIPS as described at § 414.1350(c)(6). As we discussed in the CY 2018 PFS proposed rule (82 FR 30050 through 30051), increasing the case minimum to improve measure reliability would reduce the number of clinicians assessed by the measure. This would, therefore, limit the applicability of the episode measures to larger group practices with sufficient case volume at the expense of individual providers who we wish to include in ASM. For measures to have the potential to improve performance, they should apply to as many clinicians as can be reliably measured. For a full discussion of the reliability of the 20-episode case minimum for the chronic condition EBCM measures, we refer readers to the CY 2022 PFS final rule (86 FR 65453 through 65455). We acknowledge that not all FFS beneficiaries with ASM targeted chronic conditions may be captured by the applicable EBCM given the EBCM attribution methodology. However, we believe that using an objective threshold based on these episode-based measures would appropriately identify clinicians who provide a higher volume of services related to heart failure or low back pain that would make it appropriate to hold them accountable for quality and spending. Therefore, we disagree with the comment that the 20-episode threshold would identify ASM participants who would have an underrepresented number of beneficiaries with ASM targeted chronic conditions. In the analysis we conducted to propose the 20-episode threshold, we found

that the average historical EBCM episode volume for clinicians that would likely meet the ASM participant eligibility criteria was typically 2 to 6 times higher than the 20-episode threshold.

Comment: Several commenters recommended that CMS adopt higher minimum thresholds for EBCMs. A few commenters suggested increasing the threshold to 50 episodes at the individual or practice level. Another commenter suggested 30 episodes. A commenter referenced an Agency for Healthcare Research and Quality (AHRQ) recommendation of 30 to 50 patients per physician for calculating individual performance measure scores, noting that larger samples are required for reliable comparisons; the commenter also stated that research in healthcare quality measurement confirms at least 35 to 45 observations are needed to make valid comparisons for physician quality assessment. Finally, another commenter shared their belief that given the complexities of heart failure management and the potential for multiple influencing factors, a more appropriate minimum sample size should be in the range of 100 to 200 encounters.

Response: We appreciate the commenters for their feedback on a potentially higher EBCM episode threshold in the ASM participant eligibility criteria. We acknowledge the commenter citing AHRQ's recommendation to use 30 to 50 patients per physician to calculate individual measure scores, as well as the suggestion that 35 to 45 observations would allow for valid physician-level measurement. While these recommendations are relevant to the measurement of ASM participants at the individual level, as we discussed earlier in this section of this final rule, we believe that the 20-episode threshold would be a reliable threshold to identify ASM participants who could be scored on ASM performance and, ultimately, held accountable for quality and spending. We based this threshold on the current minimum case volume for scoring the applicable EBCMs under the MIPS cost performance category described at § 414.1350(c)(6). Therefore, the proposed 20-episode threshold under ASM aligns with the MIPS/MVP measurement framework that determines when a MIPS-eligible clinician should be held accountable on EBCMs. As we discussed in the CY 2026 PFS proposed rule, increasing the episode threshold in the ASM participant eligibility criteria to 30 or 50 episodes could significantly reduce the number of potential ASM participants and create a less reliable model test (90 FR 32568). Finally, given the average number of applicable EBCM episodes that were attributed to potential ASM participants, we believe that a 100 to 200-episode threshold would be limiting and exclude a high number of potential

ASM participants that we believe should be held accountable for heart failure and low back pain outcomes and spending.

Comment: A few commenters acknowledged the CMS estimates of 43 percent of the cardiologists in the ASM heart failure cohort and 35 percent of specialists in the ASM low back pain cohort had only 20 to 29 heart failure and low back pain episodes, respectively.

Response: We appreciate the commenters for their input but would like to flag that their comments do not correctly reflect the data we provided in the CY 2026 PFS proposed rule. In the CY 2026 PFS proposed rule, we stated that increasing the EBCM episode from 20 episodes to 30 episodes would decrease the number of potentially eligible ASM participants by 43 percent for heart failure and 35 percent for low back pain relative to the 20-episode threshold (90 FR 32568). These figures represent percentage changes of eligible ASM participants between two different episode thresholds and not the percentage of likely ASM participants that had between 20 and 29 applicable EBCM episodes.

Comment: A commenter noted that the proposed 20-patient threshold for EBCMs systematically excludes rural clinicians from quality programs because rural cardiology practices maintain significantly smaller patient panels.

Response: We acknowledge the concern of potential exclusion of clinicians in small rural practices from ASM due to the size of their patient panels. We note that we have not proposed any specific exclusions for rural practices beyond that of rural areas that do not meet our definition of a mandatory geographic area; we refer readers to section III.C.2.c.(4) of this final rule for further discussion on the mandatory geographic area definition and potential exclusions. While we understand that some clinicians in small rural practices may not meet the 20 EBCM episode threshold, we believe that it would not be fair to include clinicians in ASM if we could not reliably score them on the applicable EBCM.

Comment: A commenter requested that CMS clarify eligibility related to the low back pain 20 EBCM episodes and requested CMS to publish draft ICD-10 and CPT inclusion lists at least 12 months prior to the first ASM performance year. The commenter shared their belief that early code transparency enables accurate EHR logic, clearer clinician communications, and seamless reporting for clinicians.

Response: We appreciate the commenter requesting additional clarity on the ICD-10 and CPT codes used in the EBCMs. We maintain a current Operational List of Care Episode & Patient Condition

Codes with the ICD-10 and CPT/HCPCS codes used to construct EBCM episodes on the Quality Payment Program Cost Measures page of CMS website.[181]

After consideration of public comments, we are finalizing without modification our proposal at § 512.710(b)(3) to use the EBCM episode volume threshold applicable to an ASM targeted chronic conditions as an ASM participant eligibility criterion. We are also finalizing without modification our proposal at § 512.710(e)(1) to use the heart failure EBCM as specified under MIPS to identify potential ASM heart failure participants and clinicians who have 20 or more heart failure EBCM episodes attributed to them during the calendar year 2 years prior to the applicable ASM performance year would meet the ASM participant eligibility criterion at § 512.710(b)(3). We are similarly finalizing without modification our proposal at § 512.710(e)(2) to use the low back pain EBCM as specified under MIPS to identify potential ASM low back pain participants and clinicians who have 20 or more low back pain EBCM episodes attributed to them during the calendar year 2 years prior to the applicable ASM performance year would meet the ASM participant eligibility criterion at § 512.710(b)(3).

(4) Mandatory Geographic Areas

(a) Identification of Geographic Areas

We proposed at § 512.710(f) that only clinicians in certain selected areas would be required to participate in the model. As proposed in § 512.710(f), the proposed unit of selection is CBSAs except in cases where OMB has divided large metropolitan statistical areas (MSAs) into metropolitan divisions. For these MSAs, we proposed to use these metropolitan divisions in place of the CBSA. Using metropolitan divisions rather than large MSAs would enable more precise matching of intervention and control groups by using geographic units of more comparable size, which would improve the statistical validity of our evaluation approach.

OMB Bulletin 23-01, issued on July 21, 2023, states that there are 935 CBSAs in the United States and Puerto Rico. OMB delineates MSAs and micropolitan statistical areas, which are referred to collectively as CBSAs. The general concept of the MSA and micropolitan statistical area is that of a core area containing a substantial population nucleus, together with adjacent communities having a high

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[181] 2026 Operational List of Care Episode & Patient Condition Codes (XLSX). https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.

degree of economic and social integration with that core. MSAs contain at least one urban area of 50,000 or more population; micropolitan statistical areas contain at least one urban area of at least 10,000 and less than 50,000 population.

If specified criteria are met, an MSA containing a single core with a population of 2.5 million or more may be subdivided into metropolitan divisions, which function as distinct areas within the larger metropolitan statistical area. CBSAs are composed of entire counties. There are 393 MSAs, of which 13 are subdivided into 37 metropolitan divisions, and 542 micropolitan statistical areas in the United States and Puerto Rico, as of July 2023.

We also considered using the following geographic areas as the geographic unit from which ASM participants are identified: (1) certain ZIP Codes based on their Hospital Referral Regions (HRR); or (2) certain states. We considered selecting based on HRRs for ASM. HRRs represent regional health care markets for tertiary medical care and are defined by determining where most patients were referred for major cardiovascular surgical procedures and for neurosurgery. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. While HRRs may sufficiently reflect referral patterns for heart failure episodes of care, they are less appropriate for low back pain episodes. Therefore, we decided that using CBSAs and metropolitan divisions as a geographic unit is preferable over HRRs for this model.

We also considered selecting states as the geographic unit of selection for ASM. However, we concluded that CBSAs and metropolitan divisions would provide a more granular unit of analysis, allowing for better matching of comparison areas. Additionally, selecting states would greatly reduce the number of independent geographic areas subject to selection under the model, and thus would decrease the statistical power of the model evaluation. Finally, CBSAs and metropolitan divisions straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care.

We proposed that we would select the CBSAs and metropolitan divisions through the stratified random sampling methodology described later in this section of this final rule to participate in ASM. Although CBSAs are revised periodically, we proposed to use the CBSA and metropolitan division designations in OMB Bulletin 23-01 issued on July 21, 2023 as the CBSA designations for purposes of selecting participants for this model, regardless of whether such CBSA designations have changed since

July 21, 2023, or would change at some point during the ASM test period. We believe that this approach would best maintain the consistency of the ASM participants in the model, which is crucial for our ability to evaluate the effects of the model test on quality of care and changes in Medicare spending.

As discussed later in this in section III.C.2.c.(4).(e) of this final rule, we proposed in § 512.710(f)(4) to use the ZIP Codes of the service locations of each clinician as discussed in section III.C.2.c.(4).(e) of this final rule to assign each clinician to a single CBSA or metropolitan division. Each clinician that CMS determines falls under the selected CBSA or metropolitan division, and that otherwise meets the other eligibility criteria set forth in § 512.710(b), would be required to participate in the model.

Based on our proposal to randomly select CBSAs and metropolitan divisions as ASM's mandatory geographic areas, we proposed that IP Codes and other areas not located in a CBSA or metropolitan division would not be included in the ASM selection methodology as discussed in section III.C.2.c.(4).(b) of this final rule. We note that Transforming Episode Accountability Model (TEAM), a mandatory episode-based payment model, uses CBSAs as the geographic unit of selection (as defined in § 512.515). We note that the proposed mandatory geographic areas may include some areas considered as rural areas under MIPS, which defines rural areas at § 414.1305 as a ZIP Code designated as rural by the Health Resources and Services Administration's Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

We solicited comments on our proposal to use CBSAs and metropolitan divisions as the geographic unit from which ASM participants are identified. We sought comments on our proposal to use the ZIP Codes of the service locations of each clinician as discussed in section III.C.2.c.(4).(e) of this final rule to assign each clinician to a single CBSA or metropolitan division, including ZIP Codes designated as rural by HRSA's FORHP using the most recent FORHP Eligible ZIP Code file available. We sought comment on our proposal to require all eligible clinicians within a CBSA or metropolitan division that the Innovation Center selects through the stratified random sampling methodology as part of the intervention group described in section III.C.2.c.(4).(d) in this final rule to participate in ASM. Finally, we sought comments on our proposal to use the CBSA and metropolitan division designations in OMB Bulletin 23-01 issued on July 21, 2023 as the CBSA designations for purposes of selecting participants for this model.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support the mandatory geographic area proposal citing concerns about the mandatory nature of the model, clinician inability to voluntarily opt-in, differential physician payment rates and access to quality patient care. A few commenters raised concerns about mandating rural clinicians to participate in the model. A commenter suggested that CMS finalize a voluntary participation option for clinicians within the FORHP-designated rural area. A commenter expressed concern that the model had not been piloted on a voluntary basis to assess operational feasibility, resource needs, and potential unintended consequences. Another commenter shared their belief that the proposed ASM geographic selection is too broad to test a mandatory model and encouraged CMS to limit its geographic scope initially and expand after conducting statutorily required evaluations. Another commenter voiced concern that mandatory ASM participation for specialists in selected geographic regions could stifle innovation. A few commenters recommended excluding specific states, Kentucky and Indiana, from mandatory geographic selection and cited rural health care challenges for clinicians.

Response: We appreciate commenters for their feedback on our proposed random selection of CBSAs and metropolitan divisions for mandatory participation in ASM. Mandatory participation in the model is important for ensuring a valid and robust model evaluation; allowing clinicians to opt in or opt out of the model would undermine the comparability between the intervention and comparison groups. The proposed geographic scope of ASM is important to ensure adequate statistical power to measure the effects of ASM on key outcomes. Including participants in rural areas is necessary to evaluate the impacts of the model if it were to be expanded to rural areas. We note that CBSAs with low volume of eligible episodes (that is, CBSAs with no eligible clinicians with at least 20 episodes in the reference year), which includes some rural areas, will be excluded from the model. Additionally, rural areas not assigned to a CBSA will be excluded.

Comment: A commenter recommended a voluntary approach to ASM to allow hospitals outside designated regions to participate. Another commenter recommended including the Los Angeles, Long

Beach and Anaheim CBSA in Cohort 1, and shared their belief that diverse population, concentration of specialists, and healthcare environment would serve as an environment to test the model.

Response: We appreciate the commenters for their feedback on allowing hospitals outside designated regions to participate in ASM. Allowing participants to voluntarily opt into the model would allow participants to self-select into the model; hospitals, practices, or providers who voluntarily opt in would likely differ from those who do not opt in in important but unobservable ways and would therefore undermine the comparability between the intervention and comparison groups, which would weaken the model evaluation.

Comment: A commenter supported the proposal and shared their belief that it allows for real value comparisons.

Response: We appreciate the commenter for their feedback. Allowing for meaningful comparison between the model participants and a comparison group where the model is not being implemented is an important aspect of the model design and will help us to conduct a reliable evaluation of the model.

Comment: A commenter did not support the proposal and shared their belief that the heart failure EBCM attribution method assigns patients to cardiologists practicing at a distant location, even when the patients receive most of their care locally. The commenter recommended CMS to reconsider geographic attribution when patients live over 50 miles away and are primarily treated by clinicians locally.

Response: We appreciate the comment regarding patient attribution in the heart failure EBCM. This approach is used by MIPS to attribute episodes of care to a clinician or clinician group. This method is intended to reflect meaningful clinical involvement in an episode of care but does not directly account for the geographic location of the clinician and beneficiary; we acknowledge that in some cases, it may assign an episode to a clinician practicing at a distant location. Unfortunately, this is a limitation of the claims data available for episode attribution, and CMS does not have available any viable alternative data sources for attributing episodes.

Comment: Several commenters did not support the proposed mandatory geographic area sampling procedure for various reasons. A commenter expressed concern on whether CMS' proposed approach of mandating physician participation in randomly selected regions and prohibiting it in others would produce comparable groups for evaluation over time. Another commenter recommended allowing physicians in all

CBSAs to participate, noting it would ensure fair evaluation and a more accurate quality performance assessment. A commenter suggested that CMS' proposal to randomly select a stratified sample of CBSAs for mandatory participation could raise fairness concerns, as practices in chosen regions could face unequal challenges or benefits. The commenter recommended that CMS implement risk adjustment approaches to address differences in patient populations and resources across regions. A separate? commenter shared their belief that the proposed geographic selection was too large for a mandatory model and encouraged CMS to narrow the geographic scope initially. Another commenter expressed concern that mandatory participation in ASM based on geographic location and specialty code could include physicians whose practices or patient populations are not relevant to the model's goals, such as proceduralists who lack longitudinal patient relationships necessary to impact patient outcomes. Another commenter expressed concerns about the potential impact of a mandatory design without adequate voluntary testing, particularly on smaller, independent, and rural specialists, who may often lack resources to manage two-sided risk and absorb financial losses.

Response: We appreciate the commenters for their feedback on our proposed geographic area sampling procedure. We acknowledge that participants may exit or enter the model from performance year to performance year based on changes in episode volume, but we do not anticipate that this will reduce the comparability of the comparison group over time because both intervention and comparison areas should be evenly affected.

Allowing participants to voluntarily opt into the model would undermine the comparability between the intervention and comparison groups, which would undermine the model evaluation. We acknowledge that clinicians and practices in selected regions could face challenges or benefits as part of the ASM test, but this is necessary to ensure a valid evaluation of the model test. The evaluation will use appropriate risk adjustment approaches to account for differences in patient populations and resources across regions.

We considered options for the geographic scope of the model and determined that the proposed model size is appropriate to maximize statistical power for evaluating the impacts of the model on spending and quality of care, and the proposed model size also aligns with CMS policy goals. The model limits participation to specific specialties identified as the most relevant and appropriate for inclusion for

the model's goals. As ASM is a CMS model test and based on an existing MIPS and MVP framework, we do not agree that a voluntary model test of ASM is necessary before testing a mandatory design.

After consideration of public comments, we are finalizing our proposed policy to use CBSAs and metropolitan divisions as the geographic unit for selection and to use the ZIP Codes of the service locations of each clinician as discussed in section III.C.2.c.(4).(e) of this final rule to assign each clinician to a single CBSA or metropolitan division including ZIP Codes designated as rural by HRSA's FORHP using the most recent FORHP Eligible ZIP Code file available. We are finalizing our proposed policy to require all eligible clinicians within a CBSA or metropolitan division that the Innovation Center selects through the stratified random sampling methodology as part of the intervention group described in section III.C.2.c.(4).(d) in this final rule to participate in ASM. Finally, we are finalizing our proposed policy to use the CBSA and metropolitan division designations in OMB Bulletin 23-01 issued on July 21, 2023 as the CBSA designations for purposes of selecting participants for this model. We are finalizing these provisions at § 512.710(f) and § 512.710(f)(2).

(b) Exclusion of Certain CBSAs and Metropolitan Divisions

We proposed at § 512.710(f)(1) that we would not consider certain CBSAs or metropolitan divisions for selection. Specifically, we proposed at § 512.710(f)(1)(ii) that we would exclude any CBSA or metropolitan division located entirely in U.S. territories due to challenges we would have in finding suitable geographic areas for comparison. We also proposed at § 512.710(f)(1)(i) to exclude any CBSAs or metropolitan divisions that do not have any clinicians of the mandated specialty types with at least 20 eligible episodes between January 1, 2024 and December 31, 2024 in accordance with the EBCM episode threshold described in section III.C.3.c.(3).(b) of this final rule. We believe it is unlikely for these CBSAs or metropolitan divisions to have data available for evaluation after the model starts. After applying these criteria, we expect to have approximately 600 CBSA and metropolitan divisions remain available for selection into ASM.

We considered the alternative of excluding from ASM any CBSA or metropolitan divisions located within a state or portion of a state with a commitment to participate in the Advancing All-Payer Health Equity Approaches and Development (AHEAD) model. The AHEAD model is a state-wide CMS Innovation Center model implemented under section 1115A of the Act that aims to increase investment in

primary care, provide financial stability for hospitals, and support beneficiary connections to community resources. We decided not to propose these exclusions because ASM would not interact with the payment methodology in AHEAD and may help align a broader set of clinicians towards the goals of AHEAD.

We sought comments on our proposal to exclude from selection any CBSA or metropolitan division located entirely in a U.S. territory and any CBSAs or metropolitan divisions that do not have any clinicians of the mandated specialty types with at least 20 eligible episodes between January 1, 2024 and December 31, 2024. We sought comments on the alternative to exclude AHEAD geographies from ASM's mandatory CBSA or metropolitan divisions.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters wanted clarification on whether Maryland providers, historically excluded from other CMS models, would be included or excluded from ASM.

Response: We appreciate the commenters for seeking clarification on the reason for including Maryland providers in ASM. Maryland providers will not be excluded from ASM; CBSAs and metropolitan divisions that are in Maryland (either partially or completely) will be included for random selection. We acknowledge that other CMS models have excluded Maryland from participation because of concerns about model overlap (for example, with Maryland's all-payer model). We considered excluding CBSAs that overlap with Maryland from selection for ASM but determined that concerns about model overlap were not significant enough to justify exclusion from ASM.

Comment: A commenter recommended that CMS consider excluding CBSAs in states subject to CMS' new Wasteful and Inappropriate Service Reduction (WISeR) Model. The commenter expressed concern that this would create additional burden because the WISeR Model focuses on similar low back pain services.

Response: We appreciate the commenters for their feedback on our proposed geographic area exclusions. We considered exclusions on the basis of overlap with other Innovation Center models including WISeR. Like ASM, WISeR also seeks to reduce the use of low-value services. Participants in WISeR will be companies using technologies to try to improve the review process for select services. Clinicians, including ASM participants, will not directly participate in WISeR, but may be required to

interact with the model when seeking prior authorization. However, we do not agree that overlap with WISeR will create significant burden on ASM participants to justify excluding these states from ASM.

After consideration of public comments, we are finalizing our proposed policy to exclude from selection any CBSA or metropolitan division located entirely in a U.S. territory and any CBSAs or metropolitan divisions that do not have any clinicians of the mandated specialty types with at least 20 eligible episodes between January 1, 2024 and December 31, 2024. We are finalizing these provisions at § 512.710(f)(1).

(c) Geographic Selection Methodology

To determine which CBSAs and metropolitan divisions would be included in the model, we proposed to use a stratified random sampling method to select approximately 25 percent of CBSAs and metropolitan divisions into ASM following the process described in the following two sections of this final rule. We proposed at § 512.710(f)(2) to stratify CBSAs and metropolitan divisions into mutually exclusive groups based on three CBSA/metropolitan division-level characteristics: average total Parts A and B episode spending, volume of eligible episodes, and metropolitan division status. We proposed at § 512.710(f)(2)(i) through (vi) stratifying eligible CBSAs into six mutually exclusive groups:

- Eligible CBSAs with "Low" average total episode spending (as defined below) and "Low" eligible episode volume (as defined below);
- Eligible CBSAs with "Low" average total episode spending and "High" eligible episode volume (as defined below);
- Eligible CBSAs with "High" average total episode spending (as defined below) and "Low" eligible episode volume;
- Eligible CBSAs with "High" average total episode spending and "High" eligible episode volume;
- Eligible CBSAs with "Very High" eligible episode volume (as defined below);
- Eligible metropolitan divisions.

(i) Average Total Parts A and B Episode Spending

We proposed at § 512.710(f)(2) to measure average total Medicare Parts A and B episode spending using claims data from January 1, 2024 to December 31, 2024. One of the main objectives of

ASM is to reduce spending, and therefore, it would be important to account for the significant variation in average episode spending across geographic areas. This stratification would help ensure that we can measure any variation in model effects between high and low spending areas. We proposed to use a single, pooled measure including spending for both heart failure and low back pain episodes. This would help limit the number of overall strata and we believe would allow for adequate representation of both high spending low back pain areas and high spending heart failure areas, where the potential for savings may be greatest. We proposed to categorize CBSAs into two categories based on average total parts A & B episode spending: below the median ("Low") and at-or-above the median ("High").

(ii) Volume of Eligible Episodes

We proposed at § 512.710(f)(2) to measure eligible episode volume using claims data from January 1, 2024 to December 31, 2024. We expect significant variation in the volume of eligible episodes across areas. This variation may reflect differences in other characteristics that are related to ASM performance. For example, large, active markets with a larger number of specialists may have structural advantages in performing well in ASM compared to smaller, less active markets. The proposed stratification on volume of eligible episodes would help ensure we select an adequate sample of areas with varying levels of specialty activity so that we would be able to identify statistical differences in outcomes across levels of specialty activity. This stratification would also help ensure that selected CBSAs have sufficient episode volume to support a robust evaluation. We proposed to use a single, pooled measure including both heart failure and low back pain episodes. This allows us to limit our number of stratification variables and analysis of 2023 episode-level data found that the episode volumes of the two conditions are highly correlated across CBSAs. We proposed to categorize CBSAs into three categories based on total episode volume: below median ("Low"), at-or-above median up to the 95th percentile ("High"), and the 95th percentile and above ("Very High"). We proposed to stratify out the top 5 percent of CBSAs by episode volume because of the right-skewed nature of the episode volume distribution.

(iii) Metropolitan Divisions

The largest 13 CBSAs are divided into 37 metropolitan divisions. Metropolitan divisions therefore represent a subdivision level compared to CBSAs. Additionally, these metropolitan divisions,

all belonging to CBSAs with a core population of 2.5 million or more, may have important characteristics in common beyond episode volume and average total spending. To ensure adequate representation of metropolitan divisions in the sample, we proposed to categorize metropolitan divisions into their own stratum.

We considered stratifying by other characteristics, including ACO penetration, supply of PCPs, region, rurality, and participation in the AHEAD model. We sought comments on our proposed selection strata as well as alternatives considered.

We did not receive public comments on this provision, and therefore, we are finalizing these provisions as proposed at § 512.710(f)(2).

TABLE B-D3: NUMBER OF ELIGIBLE CBSAs AND METROPOLITAN DIVISIONS BY STRATUM (2024 EBCM DATA)

Stratum Number	Average Total Parts A&B Episode Spending	Volume of Eligible Episodes	CBSA or Metropolitan Division?	Selection Probability	Estimated number of CBSAs or Metropolitan Divisions in Stratum
1	Low	Low	CBSA	40%	156
2	Low	High	CBSA	40%	117
3	High	Low	CBSA	40%	123
4	High	High	CBSA	40%	135
5	-	Very High	CBSA	40%	28
6	-	-	Metropolitan Division	40%	37

(d) Stratified Random Selection of Mandatory Geographic Areas

A representative sample of clinicians that meet eligibility requirements for the proposed ASM is necessary for a robust evaluation of the model. Testing the model in this manner would also allow us to learn more about utilization patterns of health care services and how to incentivize the improvement of quality and care coordination for chronic heart failure and low back pain. This learning could potentially inform the Quality Payment Program and the future of the MVP reporting option. Therefore, we proposed a broad, representative sample of clinicians in multiple geographic areas. We determined that the best method for obtaining the necessarily diverse, representative group of clinicians would be through stratified, random selection. A stratified, randomly selected sample would allow us to ensure statistical balance across characteristics of interest (for example, average spending and episode volume) and would provide results that applies generally to similar Medicare clinicians that submit FFS claims and treat heart

failure or low back pain and would allow for a more robust evaluation of the model. We also believe that there could be broader learnings from ASM that could apply to other conditions and specialists.

At § 512.710(f)(3), we proposed to randomly select CBSAs and metropolitan divisions for ASM from the six stratified groups described above at a 40 percent rate (that is, each CBSA and metropolitan division in each stratum has a 40 percent chance of being selected into the model). If 40 percent of a given stratum does not result in a whole number of CBSAs or metropolitan divisions, CMS would round up to the next whole number to ensure that at least 40 percent of areas from each stratum are selected. Table B-D3 provides an illustrative example of the six stratified groups based on CY 2023 data. We considered using other selection rates but based on preliminary analyses, we believe these selection rates would produce adequate sample size and participant mix for the model test. We refer readers to the regulatory impact analysis in section VII. of this final rule for further discussion on the scale of ASM and its estimated financial impact.

We conducted power analyses to identify detectable changes in total and episode spending between a potential group of CBSAs and metropolitan divisions selected for the model and a potential control group of CBSAs using a Type I error of 0.05 and Type 2 error of 0.2 (implying a power of 0.8). The analysis shows that, if 240 eligible CBSAs are selected for ASM, we would be able to detect about a 3.5 percent change in total episode spending if we look at heart failure and low back pain episodes separately. Allowing a higher Type I error of 0.25 and pooling heart failure and low back pain episodes would allow us to detect about a 1.7 percent change in total episode spending.

This model may be underpowered to detect statistically significant changes in total spending. However, the model may be more likely to generate statistically significant savings among certain low-value services or spending categories that are major cost drivers for heart failure and low back pain (for example, imaging, surgeries, hospital admissions). In a case where the model's impact on total spending is ambiguous, significant savings among these categories of spending may provide strong supporting evidence that Medicare saved money overall.

We solicited public comments on our proposed approach to random selection of CBSAs and metropolitan divisions from our proposed selection strata as well as all alternatives considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended that CMS should consider improving the ASM methodology to support the delivery of higher quality care for patients by eliminating the proposed limit of 240 for the number of randomly selected CBSAs and metropolitan divisions.

Response: We did not propose a limit of 240 CBSAs and metropolitan divisions but instead proposed to select about 40 percent of CBSAs and metropolitan divisions that meet the criteria for inclusion in the selection, which we estimate will result in approximately 240 CBSAs and metropolitan divisions being selected. This approach helps ensure as high a degree of statistical power as possible for the evaluation while also ensuring that we have an adequate number of CBSAs and metropolitan divisions not selected into the model to draw from for the comparison group.

Comment: A commenter recommended that CMS conduct certain statistical analyses (for example: power analysis) consistent with AHRQ guidelines and international standards to achieve at least 80 percent power to detect clinically meaningful differences.

Response: We appreciate the commenter for their feedback on our statistical approach. Our approach to conducting power analyses is consistent with AHRQ guidelines and we designed the model to maximize our ability to detect meaningful differences in total spending and relevant claims-based quality measures.

After consideration of public comments, we are finalizing our proposed policy for random selection of CBSAs and metropolitan divisions from our proposed selection strata as proposed at § 512.710(f)(3).

(e) Assignment of Geographic Areas to Clinicians

We proposed at § 512.710(b)(4) that, to meet the ASM participant eligibility criteria, clinicians must be located in one of the selected mandatory geographic areas. We proposed at § 512.710(f)(4) to assign a single CBSA or metropolitan division to each clinician based on the clinician's most common episode-level service location ZIP Code for each ASM performance year. We believe that it would be appropriate to use service location data from EBCM episodes to identify the CBSA or metropolitan division of clinicians' service locations given the use of the EBCMs as part of ASM participant eligibility

criteria. As discussed in section III.C.2.c.(3).(b). of this final rule, EBCM episodes would help identify ASM participants who render a meaningful volume of services related to ASM's targeted chronic conditions. Using the service location from Medicare Part B claims of rendered services used to construct the episode as the basis for determining the service location of a clinician would keep a consistent and accurate source of data by which to make these geographic assignments. We also considered using the CBSA or metropolitan division related to the ZIP Code of the TIN to which a clinician has assigned billing rights for the purpose of determining whether a clinician furnishes ASM-related services in a mandatory geographic area. We believe that it would not be appropriate use a TIN's ZIP Code since a TIN's ZIP Code does not necessarily correlate to service location, particularly in the case of multi-site practices.

Using episode-level service location ZIP Code assignments, we proposed at § 512.710(f)(4) the following process to identify clinician-level CBSA or metropolitan division assignments:

● Identify all EBCM episodes relevant to ASM targeted chronic conditions attributed to a clinician during the calendar year 2 years before the applicable ASM performance year (or during January 1, 2024 through December 31, 2024 for initial CBSA or metropolitan division assignment).

● For each episode, establish a service location ZIP Code. An episode may consist of several Medicare Part B Claims. Not all of the ZIP Codes set forth on the Medicare Part B claims form may be the same. To determine which ZIP Code the episode would be associated with, we proposed to review all applicable Medicare Part B claims associated with the episode and identify the Medicare Part B claim line ZIP Code appearing most often. An episode could have an equal number of ZIP Codes on claims associated with the episode. We would break any ties between ZIP Codes by determining the episode's ZIP Code based on the ZIP Code on the claim with the highest total cost indicated by the total standardized allowed amount, or in instances a second tie break is needed, by using the ZIP Code on the claim with the most recent date.

● Match the ZIP Code assigned to each episode to a CBSA or metropolitan division. In other words, determine the CBSA or metropolitan division to which the episode is assigned. To do so, we proposed to use ZIP Code and CBSA/metropolitan division crosswalks published quarterly by the U.S.

Department of Housing and Urban Development.[182] Some CBSA and metropolitan division share ZIP Codes, meaning a ZIP Code could be assigned to multiple CBSAs and metropolitan divisions. In these instances, to ensure each ZIP Code is linked to a unique CBSA or metropolitan division, we would assign the ZIP Code to the CBSA or metropolitan division where the ZIP Code has the highest proportion of total addresses. For example, if ZIP-A spans CBSA-B and CBSA-C, and ZIP-A has more addresses in CBSA-B, then we would assign ZIP-A to CBSA-B. We would get the proportion of total addresses in each ZIP Code from the ZIP Code to CBSA/metropolitan division crosswalk published by the U.S. Department of Housing and Urban Development.[183] The crosswalk also subdivides the proportion of total addresses into the number of business addresses, residence addresses, and other addresses. If the proportion of total addresses within the ZIP Code is equal across CBSAs or metropolitan divisions (meaning that we cannot use the proportion of total addresses to assign a single CBSA or metropolitan division to the ZIP Code), then we would assign the ZIP Code to the CBSA and metropolitan division (if applicable) with the highest proportion of business addresses (regardless of the number of residence addresses or other addresses). We use business addresses as the tiebreaker since business addresses would represent where clinicians would practice, which aligns with our overall approach for using service location for participant identification.

● Determine the appropriate CBSA or metropolitan division for each clinician attributed applicable episodes. If the clinician is attributed multiple episodes in multiple CBSAs or metropolitan divisions, we would match the clinician with the CBSA or metropolitan division where the clinician has the most assigned episodes. If a clinician has an equal number of episodes assigned to multiple CBSAs or metropolitan divisions, we will break such a tie by matching the clinician to the CBSA or metropolitan division that has the highest total risk-adjusted spending across all episodes assigned to each CBSA or metropolitan division. If a second tie break is needed, we would match the clinician to the CBSA or metropolitan division that has episodes with the more recent dates. For example, if a clinician has an equal number of episodes in CBSA-B and CBSA-C, but the episodes in CBSA-B collectively have a

[182] https://www.huduser.gov/portal/datasets/usps_crosswalk.html.
[183] https://www.huduser.gov/portal/datasets/usps_crosswalk.html.

higher total risk-adjusted spending compared to all episodes in CBSA-C, then the clinician would be matched to CBSA-B.

We solicited comments on our proposed process at § 512.710(f)(4) for determining the CBSA or metropolitan division of a clinician for each ASM performance year using EBCM data for the purposes of determining whether a clinician is located within a mandatory geographic area for each ASM performance year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed use of episode-claims-based service ZIP Code to assign a CBSA or metropolitan division code to clinicians. A commenter recommended making the attribution method easier to track and identify ASM areas and patients. Another commenter acknowledged CMS for detailing the steps to assign providers performing services under multiple TINs within the same ZIP Code and participation requirements based on CBSA selections.

Response: We appreciate commenters for their support of our proposal to use the ZIP Code on claims used to construct EBCM episodes in assigning a CBSA or metropolitan division code to clinicians. Regarding the suggestion to make it easier to track and identify ASM areas and patients, the selected CBSAs and metropolitan divisions will not change during the model test period. Regarding the comment on how geographic area assignments would work for providers performing services under multiple TINs with the same ZIP Code, we would treat each TIN and NPI combination as separate entities to which we would assign a geographic area. We would assign each TIN and NPI combination a CBSA or metropolitan division based on the ZIP Code on the claims used to construct each EBCM episode that is attributed to each TIN and NPI combination. Under this approach, it is possible that an NPI could be assigned to the same or different geographic area for each TIN to which they have reassigned billing rights. We believe that this approach is preferable since our goal with using the ZIP Code from claims is to identify where clinicians are furnishing services the most.

Comment: A commenter supported the proposed approach to use a specialist's geographic location with a stratified sampling methodology to identify mandatory ASM participants

Response: We appreciate the commenters for their feedback on our proposed policy for assigning geographic areas to clinicians. We believe this is the most accurate and reliable approach given data and other constraints.

After consideration of public comments, we are finalizing the ASM participant eligibility criterion at § 512.710(b)(4) as proposed. We are also finalizing our proposed policy to assign a single CBSA or metropolitan division to each clinician based on the clinician's most common episode-level service location ZIP Code for each ASM performance year as proposed at § 512.710(f)(4).

(5) Selection and Notification Process for ASM Participants

We proposed to identify ASM participants on an annual basis. At § 512.710(g) we proposed to identify all clinicians furnishing covered services in accordance with the ASM participant eligibility criteria specified in section III.C.2.c.(3) of this final rule using applicable data from 2 calendar years prior to each ASM performance year. We also proposed that a clinician selected for participation for any ASM performance year would be considered an ASM participant for the remainder of the model.

We proposed at § 512.710(g)(1)(i), for the 2027 ASM performance year/2029 ASM payment year only, to identify preliminarily eligible ASM participants using the ASM participant eligibility criteria and applicable data from calendar year 2024. If ASM is finalized as proposed, we proposed to make public preliminarily eligible ASM participants in a form and manner determined by CMS. We expected to release this information by the end of CY 2025. Then, to finalize the ASM participants for the 2027 ASM performance year/2029 ASM payment year, we proposed at § 512.710(g)(1)(ii) to confirm that the preliminarily eligible ASM participants continue to meet the ASM participant eligibility criteria using more recent data from calendar year 2025. We proposed to make public the selected ASM participants for the 2027 ASM performance year/2029 ASM payment year in a form and manner determined by CMS. We expect to release this information by the end of July 2026, preceding the start of the 2027 ASM performance year/2029 ASM payment year. We believe that notifying preliminarily eligible ASM participants well before the start of the first ASM performance year in 2027 will provide ample time to become familiar with ASM requirements, make practice adjustments, and prepare for reporting of the required measures and data.

We also considered not releasing the preliminarily eligible ASM participants for the 2027 ASM performance year/2029 ASM payment year and, instead, only using applicable data from the 2025 calendar year to identify the final ASM participants for the 2027 ASM performance year/2029 ASM payment year. However, this alternative reduces the amount of time for ASM participants to prepare for the first ASM performance year and would potentially increase the operational burden for clinicians selected for the model.

We proposed at § 512.710(g)(2)(i), for each ASM performance year beginning with the 2028 ASM performance year/2030 ASM payment year, to confirm that ASM participants continue to meet ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. If an ASM participant does not meet the ASM participant eligibility criteria for the upcoming ASM performance year, then they would not be required to meet applicable ASM reporting requirements for the applicable ASM performance year. Further, waivers, including the MIPS waiver described at § 512.775, would no longer apply to the ASM participant, and, if applicable, the ASM participant would be required to participate in MIPS.

Beginning with the 2028 ASM performance year/2030 ASM payment year, we proposed at § 512.710(g)(2)(ii) to identify additional clinicians not previously identified as ASM participants who meet the ASM participant eligibility criteria at § 512.710(b) for the upcoming ASM performance year/ASM payment year using data from the calendar year 2 years prior to the applicable ASM performance year.

We proposed that CMS would make public the final list of ASM participants for a given ASM performance year annually in a form and manner determined by CMS. We stated our intention to release this information by the end of July in the year preceding the start of the applicable ASM performance year. We believe that annually identifying clinicians who meet the ASM participant eligibility criteria will ensure we are accurately selecting ASM participants. That is, ASM participants will continue to be of the required specialty type and meet the EBCM episode volume thresholds year-over-year. This approach to selecting ASM participants also allows us to account for movement of ASM participants to different practices within mandatory geographic areas and allows new ASM participants into the model over the

ASM test period. We also believe that this approach will allow ASM to maintain an appropriate number of ASM participants over the ASM test period to produce a reliable model test.

We considered an alternative approach of establishing a fixed list of ASM participants for all ASM performance years. Under this alternative, we stated we would first identify ASM participants as clinicians that meet the ASM participant eligibility criteria using applicable data from the 2024 calendar year for the 2027 ASM performance year/2029 ASM payment year and release a list of preliminarily eligible ASM participants. We would then finalize the ASM participants for the 2027 ASM performance year/2029 ASM payment year using applicable data from the 2025 calendar year. Beginning in the 2028 ASM performance year/2030 ASM payment year, we would reconfirm that the final ASM participants identified for the 2027 ASM performance year/2029 ASM payment year continue to meet the ASM participant eligibility criteria for each ASM performance year thereafter using applicable data from 2 calendar years before the applicable ASM performance year. Under this alternative, we would not identify new ASM participants over the course of the ASM model test period. We stated that repeatedly reconfirming that the initial ASM participants continue to meet ASM participant eligibility criteria for each ASM performance year would result in attrition of any ASM participant who changes their association with a practice (that is, assigns billing rights to a different TIN) after the first ASM performance year based on our proposed identification of ASM participants at the TIN/NPI level. Accordingly, we believe that this alternative fixed-list approach would reduce the number of ASM participants over the ASM test period and the magnitude of this potential decrease could undermine the reliability of the model test.

We solicited comments on our proposed approach for selecting and notifying ASM participants at § 512.710(g). We also sought comments on not producing a preliminary list of ASM participants using 2024 data for the 2027 ASM performance year/2029 ASM payment year and only identifying the final ASM participants using applicable data from the 2025 calendar year. We also sought comments on whether we should use a fixed list of ASM participants for all ASM performance years.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to evaluate the selection criteria for ASM participants on an annual basis.

Response: We appreciate the commenters for their support of evaluating ASM participant eligibility criteria annually.

Comment: A commenter recommended CMS to provide additional guidance on how clinicians would be selected for mandatory participation in ASM.

Response: We intend to release additional guidance about the ASM participant eligibility criteria following the publication of this final rule. We also intend to release the list of preliminarily eligible ASM participants for the CY 2027 ASM performance year in early 2026 through the CMS website. We refer the commenter to the ASM participant eligibility criteria review section III.C.2.c. of this final rule and the accompanying regulations at § 512.710 for the final provisions related to mandatory participation.

Comment: A commenter supported the proposed release of a preliminary ASM participant list using data from CY 2024, noting that it would provide useful information for potential ASM participants. The commenter recommended that CMS provide multiple data snapshots throughout the year, similar to the Quality Payment Program Qualifying APM Participant status approach, to provide more accurate and timely participant data. Another commenter expressed concerns of a 2-year lag on episode attribution for the proposed preliminary ASM participant list using data from CY 2024. The commenter also noted that historical data may be insufficient to assess clinician practice patterns for a prospective model.

Response: We appreciate the support of our proposal to release the preliminary ASM participant list in advance. We recognize that releasing multiple data snapshots through the year, similar to the Quality Payment Program, would provide more timely data on potential eligibility to a clinician. We also recognize the challenges of lagged data. However, we believe that EBCM data is the most appropriate and objective criteria by which to identify clinicians for ASM participation. Because EBCMs are constructed at the completion of each calendar year, the data only becomes available on an annual basis. In order to provide as much advanced notice as possible to ASM participants, we must rely on EBCM data produced using data two years prior to the ASM performance year. Specifically, we will use the EBCM data from the year prior to notification, which takes place the year prior to the ASM performance year.

Comment: A few commenters expressed concern that ASM participants with only a few EBCM episodes may change ASM participation status year over year and not know if they were eligible until the end of the year. A commenter shared their belief that this could be confusing for ASM participants and possibly deter potential ASM participants from taking on more beneficiaries with heart failure or low back pain.

Response: We appreciate the commenters for their input. Use of an objective criteria, such as the 20 EBCM episode threshold, would mean that ASM participation status could change year-over-year depending on the volume of applicable EBCM episodes attributed to the clinician. We believe that this is inherent to a model that requires mandatory participation and reevaluates eligibility for each performance year. Beyond the first ASM performance year, for which we would give approximately 1 year notice of mandatory participation, we note that we intend to notify clinicians of their mandatory ASM participation status for all subsequent ASM performance years at least 6 months prior to the start of the ASM performance year, depending on data availability. This approach would prevent clinicians from being notified of mandatory participation at the end of a given ASM performance year. We do not agree that this threshold alone would create an incentive to drop or refuse to take on more FFS beneficiaries with heart failure or low back pain. As ASM is focused on specialists whose patient panels would include a high number of FFS beneficiaries with heart failure or low back pain, we believe decisions to avoid taking on additional beneficiaries with these conditions could lead to downstream effects on the specialist's practice. Further, we believe that the potential for positive Part B payment adjustments through ASM would create an incentive for the clinician to continue to furnish services to FFS beneficiaries. We also note that we will monitor potential issues with patient access as part of ASM monitoring efforts.

Comment: A few commenters recommended CMS identify ASM participants with advance notice, establishing a clear and direct notification process for communicating to selected ASM participants. Another commenter requested CMS clarify how the Agency would communicate (for example, mail, email) with ASM participants about their inclusion in the model, considering ASM is a new model. Another commenter recommended CMS proactively reach out to solo and small practices with limited resources who may be disadvantaged by participating in a 5-year model. Another commenter

recommended CMS clarify the types of data that would be included in the ASM preliminary eligibility notification.

Response: We appreciate commenters for their input. We are committed to ensuring potential ASM participants are appropriately notified through a variety of mechanisms. We expect to post the lists of ASM participants on the ASM website, contact selected ASM participants by email using the contact information on file with CMS, and work with the appropriate specialty societies to publicize the notification processes and communicate to their members the importance of ensuring their contact information is accurate and up to date. In addition, we intend to offer resources and webinars to preliminary ASM participants beginning in CY 2026. For the 2027 ASM performance year only, we will notify preliminarily eligible ASM participants using the ASM participant eligibility criteria and applicable data from CY 2024. Although we originally expected to release this information by the end of CY 2025, we now anticipate that the list will be made public in early 2026 in a form and manner determined by CMS. We anticipate subsequently notifying the final ASM participants for the 2027 ASM performance year around July 2026 using the ASM participant eligibility criteria and applicable data from calendar year 2025. We note that only clinicians on the preliminary eligible list will be considered for inclusion on the final participant list for the 2027 ASM performance year. For subsequent years, we expect to post the list of ASM participants on the ASM website and email ASM participants approximately 6 months before the start of the applicable ASM performance year using the ASM participant eligibility criteria and applicable data from the calendar year 2 years prior to the ASM performance year. Final lists will be maintained on the ASM website and selected ASM participants will be notified by email using the person of contact and contact information on file. We expect that the participant list will include at minimum, clinician NPI, state, and applicable ASM cohort. CMS will evaluate annually whether a clinician meets the ASM participant eligibility criteria using the information available in PECOS and specialties assigned to Medicare Part B claims. To avoid potential errors, clinicians can update their PECOS information if they believe that their specialty designation does not reflect their actual clinical practice.

Comment: A few commenters did not support the proposal to notify ASM participants only 6 months prior to the start of the first ASM performance year, noting an insufficient time for clinicians to prepare for model implementation. Another commenter requested CMS finalize the ASM participant list

more than 6 months before the beginning of the first ASM performance year and notify both the individual clinicians and their TIN-level entity. Another commenter expressed concern that a 6-month advance notice would not be enough for ASM participants to prepare for new Electronic Clinical Quality Measure (eCQM) reporting.

Response: We appreciate the feedback on the timing of the release of the lists of ASM participants for each ASM performance year and the time that it would provide ASM participants to prepare for the model. As we discuss throughout this section of this final rule, we anticipate releasing the preliminary list of clinicians selected for participation for the 2027 ASM performance year based on CY 2024 data in early 2026; we would then reassess only clinicians on that list for the ASM participant eligibility criteria using CY 2025 data. We then plan to release that list 6 months before the start of the 2027 ASM performance year, providing nearly 12 months notice to potential ASM participants for the first ASM performance year. While we recognize that we intend to release the updated participant lists for subsequent ASM performance years, which could include new clinicians to the model, at least 6 months prior to the start of a given ASM performance year, we believe that clinicians who practice within a mandatory geographic area and would potentially be eligible for mandatory participation would likely be familiar with the model given our planned outreach and communication strategies. As we have discussed throughout this section of this final rule, we intend to provide educational resources throughout CY 2026 so that clinicians on the final 2027 ASM performance year participant list would be familiar with ASM's requirements and begin making the necessary adjustments, such as for eCQM reporting, to their workflows and systems.

After consideration of public comments, we are finalizing our proposed provisions related to identification and notification of ASM participants as proposed at § 512.710(g). In particular, we are finalizing our proposal to produce a preliminary list of ASM participants using 2024 data for the 2027 ASM performance year/2029 ASM payment year as well as identifying the final ASM participants using applicable data from the 2025 calendar year as proposed. We are also finalizing as proposed to reassess clinicians for ASM participation annually, rather than use a fixed list of ASM participants for all ASM performance years.

d. Performance Assessment Approach, Data Submission Requirements, and ASM Performance Category Requirements and Scoring

As discussed in the CY 2026 PFS proposed rule (90 FR 32560 through 90 FR 32561), we proposed to use the MVP framework, including its performance categories, to assess ASM participant performance related to improving quality of care and reducing low-value care related ASM targeted chronic conditions. We believe this framework offers a tested performance assessment framework to use in creating value-based incentives for ASM participants. In this section of this final rule, we discuss the performance measures and activities that will be used to assess the performance of ASM participants in four ASM performance categories of (1) quality, (2) cost, (3) improvement activities, and (4) Promoting Interoperability. We proposed to define at § 512.705 in the CY 2026 proposed rule the "ASM performance category" as a group of applicable measures or activities used to assess an ASM participant's performance on quality, cost, improvement activities, or Promoting Interoperability. Tying a clinician's performance to certain measures and activities (as discussed below) in these performance categories would support ASM goals, as discussed in section III.C.1 of this final rule, of decreasing the cost of care for beneficiaries with ASM's targeted chronic conditions as well as improving quality care as measured through a focused measure set relevant to ASM's clinical specialties and targeted chronic conditions.

● The quality ASM performance category would assess the quality of care ASM participants delivered by measuring health care processes, outcomes, and patient experiences of care with the goal of improving the quality of care for beneficiaries with ASM's targeted chronic conditions.

● The cost ASM performance category would assess the efficiency and cost-effectiveness of care provided to Medicare beneficiaries with ASM targeted chronic conditions with the goal of providing more cost-efficient care to generate cost savings.

● The improvement activities ASM performance category would assess ASM participants in their efforts to make practice improvements that improve population health, enhance patient experiences and outcomes, reduce cost of care, and improve clinician experience. To meet ASM's practice improvement goals, ASM's improvement activities would incentivize practice improvements that would strengthen care

management and processes related to ASM's targeted chronic conditions and would incentivize stronger integration between specialist and PCPs.

● The Promoting Interoperability ASM performance category would assess ASM participants in their efforts to promote patient engagement and electronic exchange of information using CEHRT to enhance quality of care and reduce costs through more effective upstream chronic condition management and care integration related to ASM's targeted chronic conditions. Under ASM, CEHRT should meet the requirements set forth in § 414.1305, except all instances of references to MIPS are to be replaced with references to ASM.

As further discussed in the CY 2026 proposed rule (90 FR 32576 through 32586), we proposed for the quality ASM performance category, cost ASM performance category, and promoting interoperability ASM performance category, to draw measures and activities from specific MVPs related to each of ASM's targeted chronic conditions to identify a cohesive set of vetted and clinically relevant measures and activities that would allow us to appropriately assess ASM participants on the care they deliver related to ASM's targeted chronic conditions. Using the same measures would mean the many ASM participants would already be familiar with the required measures and activities proposed in each of the ASM performance categories. However, as discussed in the CY 2026 PFS proposed rule (90 FR 32574 through 32576 and 90 FR 32604 through 32615), comparing performance on these measures and activities as measured by ASM performance category and final scores within each ASM cohort would result in payment adjustments based on direct peer-to-peer comparisons of similar specialists. For some ASM performance categories, we proposed to include measures from outside of the relevant MVP, such as from the broader inventory of MIPS measures, when we believe there is a clinically justifiable rationale for including such a measure. We proposed ASM-specific measures or activities in limited circumstances when we believe there is rationale for assessing performance or creating an incentive for practice improvement specific to ASM's targeted chronic conditions. For example, the improvement activities ASM performance category, as discussed in the CY 2026 PFS proposed rule (90 FR 32589 through 32594), includes ASM-specific improvement activities.

We also discussed how we proposed to score each ASM performance category within each of the ASM performance category sections within this section of this final rule. While many of the proposed

scoring policies draw from MIPS, we proposed scoring policies that simplify some existing policies. As a mandatory model, simplification of scoring compared to some MIPS and MVP policies would make it easier for the ASM participant to understand how their performance in each of the ASM performance categories contributes to their final score and resulting payment adjustment. As part of this simplification, our proposed scoring policies ensure that each ASM participant would at minimum be measured on quality and cost, with further scoring adjustments based on performance in the improvement activities and Promoting Interoperability ASM performance categories, to determine payment adjustments.

As discussed in section III.C.2.e of this final rule, we plan to calculate a final score based on the quality, cost, improvement activities, and Promoting Interoperability performance categories scores for each ASM participant for each ASM performance year. The scores in the quality and cost ASM performance categories would positively impact the ASM final score while performance in the improvement activities and Promoting Interoperability ASM performance categories could result in negative scoring adjustments to the ASM final score.

In the following section III.C.2.d.(1).(a) of this final rule, we first discuss the ASM performance assessment approach. We then discuss data submission requirements applicable across the ASM performance categories in section III.C.2.d.(1).(b) of this final rule. Finally, we discuss specific requirements and scoring policies for each of the four ASM performance categories in sections III.C.2.d.(2) through III.C.2.d.(5) of this final rule.

(1) Performance Assessment and Data Submission Requirements

(a) ASM Performance Categories

We proposed in the CY 2026 proposed rule at § 512.715(a)(1) through (3) that CMS uses the performance measures and activities described under §§ 512.725(b) and (c), 512.730(b), 512.735(b), and 512.740(b) to assess ASM participants in the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories. As discussed in section III.C.1 of this final rule, we believe that these ASM performance categories taken together would improve the quality of care and produce cost savings related to ASM's chronic conditions. Further, we believe that, taken together, the ASM performance categories provide a comprehensive understanding of an ASM participant's management of their beneficiaries' targeted chronic conditions.

We also believe that ASM participants, because of participation in other CMS programs including MIPS, would already be familiar with reporting (1) quality; (2) cost; (3) improvement activities; and (4) Promoting Interoperability performance categories to determine a final score. This proposed structure is similar to the performance assessment approach of other CMS programs like the MIPS reporting option of the Quality Payment Program. MIPS assesses the performance of MIPS eligible clinicians across four performance categories and then determines a MIPS payment adjustment factor that applies to the clinician's Medicare Part B payments for covered professional services finalized at §§ 414.1380(a) and 414.1405(a) and as defined at § 414.1305.

Under the proposed ASM performance categories, the value of care provided to chronic care patients would be assessed through performance in the quality and cost performance categories, supported by performance in the improvement activities and Promoting Interoperability performance categories. Measures and activities CMS selects to assess an ASM's performance across the quality ASM performance category and cost ASM performance category would assess the value of care directly furnished to chronic care patients. Measuring ASM participants' cost and quality performance ensures that Medicare beneficiaries are receiving clinically appropriate, comprehensive, high-value care. Measuring cost and quality is essential to measuring the value of care provided to Medicare beneficiaries with chronic conditions. The improvement activities ASM performance category incentivizes care coordination and collaboration between specialty medicine and primary care, creating new opportunities for both groups playing vital roles in care management and coordination. And lastly, the Promoting Interoperability ASM performance category enables meaningful EHR use, the reporting of clinical quality measures, including electronic clinical quality measures (eCQMs) and continuous practice-based quality improvement and care transformation.

We believe that ASM's more targeted approach to performance assessment where we evaluate ASM participants within each ASM cohort across the ASM performance categories --(1) on a set of relevant performance measures that they are required to report; and (2) among clinicians furnishing similar sets of services, would produce final scores and subsequent payment adjustments, as described in section III.C.2.f of this final rule, that are more reflective of clinician performance. A more targeted approach to measurement would also offer more insight into how clinical decisions and processes, such as

care coordination, affect patient outcomes. We believe this insight is necessary to support and incentivize accountable care, increasing beneficiary access to coordinated specialty care. Furthermore, equipped with more specialty-relevant performance information through participation in ASM, we expect clinicians would be more likely to invest resources in pursuit of better outcomes, reducing the incidence of poor outcomes arising from care fragmentation, ultimately resulting in better care for patients.

We proposed at § 512.715(a), as further described in §§ 512.725, 512.730, 512.735, and 512.740, that ASM participants would receive a specific number of points for their performance on each measure or activity within an ASM performance category. CMS assigns the total number of points that a measure or activity may receive. The total score across all four performance categories that an ASM participant may receive is capped at 100 points. The number of points awarded for an ASM's performance on a measure or activity corresponds to the level of performance, the higher the points, the better the performance. We proposed to define at § 512.705 "ASM performance category score" as the assessment of each ASM participant's performance on the applicable measures and activities for a performance category during an ASM performance year based on the policies proposed at §§ 512.715, 512.725, 512.730, 512.735, and 512.740. As further described later in this section of this final rule, CMS would, using an ASM participant's ASM performance category scores across all ASM performance categories, calculate an ASM participant's final score for an ASM performance year / ASM payment year in accordance with § 512.745.

We proposed at § 512.715(b)(1) to use Medicare claims data and administrative data to calculate some measures included in the quality and cost ASM performance categories under §§ 512.725 and 512.730. We proposed at § 512.715(b)(2) that we use other model-specific data reported by ASM participants to calculate measure or activity scores for the quality, improvement activities, and Promoting Interoperability ASM performance categories under §§ 512.725, 512.735, and 512.740.

We solicited feedback from the public on our proposal to assess ASM participant performance across four ASM performance categories: (1) quality; (2) cost; (3) improvement activities; and (4) promoting interoperability. We sought comments on our proposal at § 512.715(a) to set and assign specific points on measures or activities in each ASM performance category and to calculate a final score using points received across all four ASM performance categories as described at § 512.745. Finally, we

sought comments on our proposal at § 512.715(b) to use Medicare claims, administrative data, and model-specific data reported by an ASM participant to calculate measure or activity scores used to calculate ASM performance category scores.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to use the four ASM performance categories for assessing the performance of ASM participants, noting that this approach would align the ASM performance framework with existing reporting programs and promote consistency in reporting. The commenters shared their belief that the proposed alignment would facilitate a smoother transition to ASM for clinicians and developers and increase participation in ASM.

Response: We appreciate the commenters for their support of the four ASM performance categories assessing performance. We, like the commenters, believe that aligning our performance framework with existing quality reporting programs will facilitate an easier transition into ASM.

Comment: A few commenters supported the proposed approach for ASM performance assessment and recommended that CMS should fully align ASM measure sets and scoring methodology with current MIPS reporting requirements, where feasible, to prevent duplicative reporting and ensure consistency across programs. A commenter recommended that CMS exclude from ASM any measure not included in MIPS or MIPS MVPs, to ensure alignment of measures for specialists across all reporting programs.

Response: We appreciate the commenters for their support of ASM's performance assessment framework. We note that all quality and cost measures being finalized for use in ASM in this final rule are already used in MIPS. However, we proposed different scoring policies for ASM performance categories compared to MIPS. Given ASM is a mandatory model that requires the reporting of a specific set of measures, compared to MIPS that allows for more flexibility in which measures a MIPS eligible clinician chooses to report, we believe that our scoring policies are fit-for-purpose so ASM participants will more easily understand how their performance will be determined under ASM. As a mandatory model, we also designed our scoring policies so that we ensure that quality and cost performance is factored into every

participant's final score, which we believe aligns with holding all ASM participants accountable for quality and cost.

Comment: A few commenters did not support the proposed approach for ASM performance assessment using the four ASM performance categories. A commenter expressed concerns regarding ASM's approach to measuring specialist care, noting that a one-size-fits-all method is inadequate, and recommended CMS should assess performance at the episode level for more accuracy. Another commenter noted specialists' concerns that the proposed ASM design based on the MVP framework relies on measures that are not relevant to low back pain and heart failure.

Response: We appreciate the commenters for sharing their concerns regarding ASM's four performance categories. We stress that though not all performance categories measure performance at the episode level, the cost performance category is evaluated at the episode level, which represents 50 percent of an ASM participant's final score. We believe a combination of episode-level cost scoring plus individual-level scoring of quality (or group-level in the case of small practices), in addition to improvement activities and Promoting Interoperability scores, is appropriate for determining overall participant performance. We also note that many of the selected measures, such as those finalized in the quality and cost measure sets, were chosen specifically for their relevance to ASM's targeted chronic conditions. The Promoting Interoperability and improvement activities ASM performance categories, though not condition-specific, are aimed at spurring transformational changes that support better quality care and lower costs.

Comment: A commenter expressed concern that ASM does not connect quality and cost measures in a meaningful way and recommended that CMS work with interested parties to identify better strategies for measuring quality and cost to ensure more accurate value-based evaluations of care.

Response: We appreciate the commenter for their comment but disagree because we believe that there is an alignment between the quality and cost measures applicable for each ASM cohort. Though not directly scored together, ASM's quality and cost performance categories are reflective of one another. For example, we believe that the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure (MIPS Q492) quality measure will account for inappropriate withholding of care if a participant were to attempt to improve their cost performance through

withholding of care. Additionally, the Low Back Pain Functional Status Change for Patients with Low Back Impairments (MIPS Q220) quality measure would result in a lower score for an ASM participant if they attempted to inappropriately limit necessary care to improve their cost performance score.

Comment: A commenter recommended either removing the improvement activities requirement or allowing flexibility in its selection, noting mandatory requirements for improvement activities would increase the burden on individual clinicians.

Response: We appreciate the commenter for sharing their concerns regarding the improvement activities ASM performance category measure. We believe that the improvement activities ASM performance category promotes collaboration between specialty and PCPs, opening new avenues for both to enhance their essential roles in patient care management and coordination. Ultimately, to lead to improved longitudinal care management, we believe it best to include the four ASM performance categories as proposed.

Comment: A commenter acknowledged CMS' approach to reduce the number of required reporting measures under ASM, noting that this change could decrease administrative burden and encourage greater clinician participation in ASM. Another commenter expressed concern that the manual clinical quality measure (CQM) reporting requirement could impose additional administrative burden as it would require working with a new external vendor.

Response: We appreciate the commenters for their support of our quality reporting measures. Though we acknowledge that reporting of manual clinical quality measures may create additional workstreams for ASM providers, we believe that those quality measures are important to evaluate the care provided by each ASM participant. Whenever possible, we attempted to lessen reporting burdens placed on ASM participants but in this instance the measures that require CQM reporting were selected because of their relevance to the participant's specialty and chronic condition that they manage. We note that several required quality measures have eCQMs collection types, which reduces burden, and that we are including an administrative claims-based measure for each cohort's quality measure set.

Comment: A few commenters expressed concern that ASM relies heavily on MIPS infrastructure and transfers several existing challenges including the lack of adequate outcome measures, lack of insight on performance that facilitates improvement, and a misalignment between cost and quality measures. The

commenters suggested CMS to examine external benchmarks for what qualifies as a "good" quality measure score, for all measures including topped out measures, and reward high performers and improvement. The commenters suggested that CMS could exclude quality measures with consistently high performance.

Response: We appreciate the commenters for sharing their concerns that ASM, through its reliance on MIPS, has imported some of the same challenges facing MIPS. We believe that policies unique to ASM address some of the commenters' concerns. ASM's quality measure set includes at least one outcome measure in each cohort as described in sections III.C.2.d.(2).(b).(i) and III.C.2.d.(2).(c).(i) of this final rule. Additionally, ASM's quality and cost structure does in fact create alignment across performance categories. As it relates to topped-out measure status and measures with high performance, we will continue to monitor during initial ASM performance years before designating an ASM measure with topped out status. We are also engaging in multiple benchmark methodologies to facilitate that decision. We also note that topped-out status under MIPS may not equate to topped-out status under ASM because MIPS eligible clinicians can choose to report quality measures on which they perform well; in ASM, the mandatory nature of the quality measures may lead to a different distribution of quality measure scores.

After consideration of public comments on ASM's four performance categories, we are finalizing the definitions of "ASM performance category" and "ASM performance category score" as proposed at § 512.705. We are also finalizing ASM's performance category approach as proposed at § 512.715(a) and finalizing ASM's use of Medicare claims, administrative data, and model-specific data reported by an ASM participant to calculate measure or activity scores as proposed at § 512.715(b).

(b) Data Submission Requirements

We proposed at § 512.720 that ASM participants would be required to submit data on the measures and activities for the quality, improvement activities, and Promoting Interoperability ASM performance categories in accordance with each ASM performance categories described in §§ 512.725, 512.735, and 512.740. As further discussed in this section, we proposed to align some data submission requirements under this model with the data submission requirements under MIPS as defined at § 414.1325. We believe that the use of similar processes and "submission types "—which we proposed to

define at § 512.705 as the mechanism by which the ASM submitter submits data to us in the form and manner specified by us, including, but not limited to: (1) direct; (2) log in and upload; and (3) log in and attest—would limit confusion and burden for those ASM participants that have previously participated in MIPS. We also intend to provide further resources on the exact data submission procedures prior to the first data submission deadline for the 2027 ASM performance year.

We proposed that ASM participants must submit data at the same level at which they are identified in the model. Since we proposed identifying ASM participants at the TIN/NPI level (as outlined in section III.C.2.c.(3).(a).(i). of this final rule), we likewise proposed that each ASM participant would be required to submit data for each ASM performance category at this same TIN/NPI level, unless specifically stated otherwise within the requirements for a particular performance category. Alignment between participant identification and data submission levels is necessary for a mandatory model and supports our goal of making accurate comparisons between similar participants. This approach differs from MIPS, which offers various reporting options (such as group, subgroup, or APM entity as defined in § 414.1305). We have determined that allowing multiple reporting configurations would undermine ASM's design objective of creating clear peer-to-peer performance comparisons for determining payment adjustments.

We recognize that some of the required measures and attestations in each ASM performance category may reflect practice-level activities. We, therefore, considered whether to allow submission of required measures and attestations for the improvement activities and Promoting Interoperability ASM performance categories at the TIN level. We believe that it is more appropriate to align the data submission level across all the ASM performance categories instead of having some ASM performance categories with data submitted at the TIN/NPI level and others at the TIN level. Alignment of submission level across all ASM performance categories supports our goal of making like-to-like performance comparisons to determine payment adjustments.

We received public comments on our general data submission requirements and our proposal that ASM participants must submit data at the individual clinician level (TIN/NPI) for ASM performance categories. The following is a summary of the comments we received and our responses.

Comment: A commenter generally supported the proposed ASM data submission requirements.

Response: We appreciate the commenter for their support of the ASM data submission requirements.

Comment: Several commenters did not support the proposal requiring ASM participants to report on a fixed subset of measures and activities applicable to an ASM cohort for the entire duration of the model. The commenters recommended that similar to MVPs, ASM participants should be allowed to select the measures and activities that are most relevant to their practice and patient population. A few commenters recommended that CMS should offer flexibility for ASM participants to select between 3 and 5 quality measures relevant to their patients. Another commenter recommended allowing 3 out of 4 quality measures in an ASM cohort. Another commenter expressed concern that requiring clinicians to report measures outside their scope of practice undermines CMS' goal of aligning measurement with clinically meaningful outcomes. A commenter expressed concern that that not every measure applies to every patient, leading to missed data, exclusion bias, and increased reporting burden. Another commenter shared their belief that creating flexibility in measure selection would make reporting more meaningful and clinically relevant while reducing unnecessary reporting burden. Additionally, a commenter expressed concern that clinicians and practices have limited control over which data are collected regardless of the organization's size.

Response: We appreciate the commenters for their feedback on ASM's requirement to report on a fixed set of measures and activities applicable to each ASM cohort. We disagree that ASM participants should have flexibility to report measures, such as in MVPs, as we believe that more focused performance assessment on a clinically relevant measure set for heart failure or low back pain is important for creating accountability for outcomes and spending related to these conditions. Additionally, ASM will test whether more like-to-like comparisons of performance can lead to more meaningful incentives; allowing for flexibility in reporting of measures and activities would undermine this test. We do not believe that the required measures or activities would be out of scope for the types of specialists that we have identified. We carefully selected measures and activities to be clinically relevant and achievable by ASM participants, primarily drawing from existing programs like MIPS to maintain participant familiarity with ASM's requirements. In addition to familiarity with many of the ASM performance category

requirements, we believe that the inclusion of eCQMs and administrative claims-based quality measures, as well as the EBCMs calculated by CMS for the cost ASM performance category, will reduce burden.

Comment: A few commenters supported setting ASM's unit of performance assessment at the TIN/NPI level to empower individual physicians to take the lead as it provides transparency about individual performance and accountability on quality and cost measures.

Response: We appreciate the commenters for their support of our unit of analysis and reporting level in ASM.

Comment: A few commenters expressed concern that quality measurement at the individual clinician level (TIN/NPI) is generally unreliable.

Response: We appreciate the commenters for their feedback but do not agree that quality measurement at the clinician level is unreliable as other quality reporting programs, such as MIPS, allow individual-level reporting of quality data.

Comment: Many commenters did not support the proposal requiring ASM data submission at the TIN/NPI level, noting significant administrative burden for ASM participants and their staff, particularly for those clinicians that are part of group practices and are already participating in traditional MIPS group reporting. A commenter expressed concerns about the administrative burden when a group is required to submit individual-level ASM data while the rest of the group reports measures to MIPS, potentially requiring clinicians and practices to collect ten or more measures for reporting. A few commenters recommended that CMS allow ASM participants to aggregate data at the registry-level or report as a group, virtual group, APM entity, or subgroup, particularly to maintain consistency across various reporting programs. Several commenters expressed concern that reporting at the TIN/NPI level conflicts with CMS' stated goal of promoting team-based care and care coordination which are essential for improving quality and efficiency. The commenters shared their belief that ASM group or aggregated data reporting would better represent team-based, multispecialty care; incentivize collaboration and accountability across the multidisciplinary clinician types essential for successful value-based care implementation; address low volume variations and eligibility thresholds; support health system improvements and care coordination; reduce errors; uphold contractual obligations; ensure consistency with other programs; and reduce burden. Several commenters supported the alternative to assess ASM

participants at the practice or TIN level because they believe this supports the current standard of practice, reporting would support team-based care, facility-based physicians, and clinicians participating in an ACO or AAPM. A few commenters specifically recommended that the improvement activities and Promoting Interoperability performance categories be attested to at the group level. A commenter also shared their belief that that there should be policy flexibilities for small practices due to limited capacity for data aggregation and reporting. Another commenter indicated that it is not more burdensome for small group practices to submit at the TIN/NPI measurement level.

Response: We appreciate commenters for sharing their concerns regarding the proposal to require data submission at the TIN/NPI level and the associated burden. We recognize that reporting quality measures at the TIN/NPI level may be particularly burdensome for small practices. We also refer readers to section III.C.2.d.(e).(4) of this final rule for ASM's definition of a "small practice" (that is, a single practice with 15 or fewer NPIs) and further discussion on comments we received related to ASM participants in small practices and the small practice scoring adjustment. We agree with the commenter's suggestion that we should adopt some data submission policy flexibilities for small practices given the challenges they may face in data reporting. Given that we considered TIN-level reporting for the improvement activities and Promoting Interoperability ASM performance categories, and that we received specific feedback from commenters to provide policy flexibilities for small practices because of the burden related to data aggregation and reporting, we are modifying our proposal to allow ASM participants in small practices to report the quality measures in the ASM performance category at the TIN-level. We believe this would reduce burden for small practices. We will monitor the performance of these small practices to determine whether there is a future state in which we could reconsider mandatory TIN-NPI-level reporting of quality measures for small practices. We believe that ASM participants in non-small practices would have the resources and infrastructure to report the quality measures in the quality ASM performance category at the TIN/NPI level.

Based on commenter's feedback, we also agree that our proposal to require submission of the improvement activities and Promoting Interoperability ASM performance categories data at the TIN/NPI level could increase administrative burden for ASM participants regardless of practice size. Reporting the improvement activities and Promoting Interoperability at the TIN level may better promote team-based

care and coordination as the requirements of these ASM performance categories typically reflect work done at a practice level. Accordingly, ASM participants will report on the improvement activities and Promoting Interoperability ASM performance categories data at the TIN-level.

We acknowledge that different reporting level requirements between MIPS and ASM has the potential to increase burden for participants or practices that are reporting to both MIPS and ASM. However, we believe it necessary to appropriately measure performance and create payment adjustments that fairly represent the care provided across ASM's four performance categories.

We note that we did not consider subgroup reporting for ASM performance categories in this CY 2026 PFS proposed rule but may consider this in future notice-and-comment rulemaking.

Comment: A commenter recommended clarification on whether ASM participants would be required to submit separate individual submissions or could submit individual-level performance data within a single group submission file.

Response: We appreciate the commenters for their request for clarification. We note that each ASM participant would need to submit data for each ASM performance category at the level the performance category requires. Based on the data submission provisions we are finalizing in this final rule, we note that ASM participants will not have the flexibility to report both as an individual and as a group. While an ASM participant could submit the required data through multiple data submissions, each data submission much meet the reporting level requirements specified in § 512.720.

Comment: A commenter recommended that CMS aggregate a clinician's performance across multiple years to overcome the statistical issues associated with reporting at the individual clinician level for ASM participants who treat a small number of patients that trigger an episode.

Response: We appreciate the commenter for their recommendation to aggregate a clinician's performance across multiple years. As described in section III.C.2.(c).(3) of this final rule, our ASM participant eligibility criteria require that a clinician be attributed at least 20 EBCMs applicable to their specialty using the applicable year of data used to evaluate the EBCM criterion. We believe that this criterion means that identified ASM participants would reliably meet the quality and cost case minimums for the required quality and cost measures during an ASM performance year. Further, our quality and cost ASM performance category scoring policies account for situations in which an ASM participant does not

meet the case minimums for quality or cost measures, including accounting for situations in which the ASM participant cannot be scored on either the quality or cost measures. We refer readers to sections III.C.2.d.(2).(h)., III.C.2.d.(3).(f)., and III.C.2.e.(2). of this final rule for further discussion on the quality, cost, and final scoring policies related to case minimums.

Comment: A commenter recommended that both attribution and evaluation of beneficiaries should be conducted at the TIN/NPI level. The commenter shared their belief that clinicians and practices should be held accountable for care delivered within their TIN, noting that aligning ASM reporting and evaluation at the same level is essential for accurate and fair performance assessments.

Response: We appreciate the commenters for their recommendation regarding the attribution and evaluation of beneficiaries at the TIN/NPI level. We note that we use EBCMs attributed at the TIN/NPI level for determining whether a clinician will meet the ASM participant eligibility criterion for minimum EBCM episode volume and for scoring the ASM participant's performance in the cost ASM performance category. Each TIN/NPI-attributed EBCM episode is attributed to a single beneficiary. As discussed earlier in this section of this final rule, with the exception of ASM participants in small practices due to the unique challenges they may face in data aggregation and reporting, aligning reporting and evaluation of quality and cost measures at the TIN/NPI level can make for fairer performance assessments. However, we believe allowing TIN-level reporting of improvement activities and Promoting Interoperability requirements for all ASM participants—because they primarily reflect practice-level efforts and infrastructure—as well as TIN-level reporting of quality measures for ASM participants in small practices will reduce the reporting burden on ASM participants without undermining ASM's performance assessment approach.

Comment: A commenter believed that required reporting for each of a clinician's TIN/NPI combinations would create redundant work and documentation, confusion, unneeded complexity, and increased costs. The commenter recommended adopting the MIPS structure of calculating a clinician's score for each TIN and then selecting the higher score and omitting the lower scores for assessment and comparison.

Response: We appreciate the commenter for their feedback. We believe that the commenter is referring to a situation where we identify a single clinician (that is, represented by one NPI) as multiple

ASM participants under multiple TINs. As we discussed in section III.C.2.c.(3) of this final rule, we believe that this would be a rare but not impossible occurrence. Based on our participant identification approach, we believe that it is appropriate to hold that clinician accountable for the care they provide related to the applicable condition under each of the TINs for which we identify them as an ASM participant. While we did not consider a provision where we would use that NPI's highest scores from all their TIN/NPI submission, we do not believe this aligns with the performance assessment and incentive structure we are creating under ASM. Should we consider such an approach in the future, we would do in notice-and-comment rulemaking.

We also proposed that data can be submitted on behalf of the ASM participant by an entity or individual designated to submit data to CMS, including a third-party intermediary as described in § 512.720(a), on behalf of the ASM participant. We proposed at § 512.705 to use with the definition of third-party intermediary set forth in MIPS at § 414.1305 to align the data submission policies for third party intermediaries between MIPS and ASM.

We received comments on the proposal to allow third-party intermediaries to submit data on behalf of an ASM participants. The following is a summary of those comments and our responses.

Comment: A commenter generally supported the inclusion of third-party intermediaries in ASM and recommended CMS including Qualified Clinical Data Registries (QCDRs) and Qualified Registries (QRs) in the definition of the term "third-party intermediaries" as approved data submission mechanisms for ASM. The commenter shared their belief that QCDRs and QRs are foundational partners in QPP and that small or independent practices rely on registries for policy interpretation, education, data aggregation, and technical submission management and expressed concern that omitting QCDRs and QRs could create uncertainty and disrupt established clinical workflows for ASM participants.

Response: We appreciate the comment for their general support of the inclusion of third-party intermediaries in the ASM data submission mechanisms.

Comment: A commenter supported the proposal allowing ASM data to be submitted to CMS on behalf of ASM participants by a designated entity or individual, including third-party intermediaries as described in § 512.720(a).

Response: We appreciate the commenter for their support of the ASM policy allowing data to be submitted to CMS on behalf of ASM participants by third-party intermediaries.

Comment: A commenter supported the proposal to use the definition of third-party intermediary set forth in MIPS at § 414.1305 for ASM, aligning the data submission policies for third party intermediaries between MIPS and ASM.

Response: We appreciate the commenter for their support of the ASM third party intermediary definition and the alignment of third-party intermediaries between MIPS and ASM.

Comment: A commenter recommended that CMS include an option within the annual self-nomination and qualification process for QCDRs and QRs to be certified for the ASM. The commenter shared their belief that this would provide a clear and official pathway for registries to support their clinicians in new programs.

Response: We appreciate the commenter for their recommendation for QCDRs and QRs to be certified for ASM. We note third-party intermediaries permitted to report data under MIPS would be allowed to do the same for ASM. Although we did not consider a specific provision for a QCDR or QR to be certified specifically for ASM, should we, we would do so in future notice-and-comment rulemaking.

After reviewing public comments, we are finalizing our definition of "submission type" as proposed at § 512.705.

We are also finalizing our proposal on the level at which ASM participants must submit the required data with some adjustments. ASM participants must:

● Submit applicable quality ASM performance category data at the individual clinician level (that is, TIN/NPI level) unless the ASM participant is part of a small practice as described at § 512.720(a)(1)(i),

● Submit required improvement activities at the TIN level as described at § 512.720(a)(1)(ii), and

● Submit required Promoting Interoperability data at the TIN level as described at § 512.720(a)(1)(iii).

After consideration of commenters' feedback, we are finalizing at § 512.720(f) that ASM participants who are part of a small practice may submit quality ASM performance category data at the TIN level.

We are also finalizing our proposed definition of "third-party intermediary" as proposed at § 512.705 and the proposed provision that allows third-party intermediaries to report data on behalf of an ASM participant as proposed at § 512.720(a)(1).

(i) *Quality ASM performance category data submission requirements*

For the quality ASM performance category, we proposed at § 512.720(a)(1)(i) that an ASM participant must report at least one required quality measure that is not an administrative claims-based collection type (discussed in sections III.C.2.d.(2).(b) and III.C.2.d.(2).(c) of this final rule) and meets the proposed data completeness requirement as discussed in section III.C.2.d.(2).(h).(i) of this final rule. The proposed requirements for the quality ASM performance category are similar to those required under MIPS as defined at § 414.1325(1)(i) but with the addition of meeting the data completeness requirement. We believe that the addition of the data completeness requirement ensures that we would have complete data by which to score at least one required quality measure. We also considered that an ASM participant must report complete data for at least 2, at least 3, or all required quality measures that are not administrative claims-based collection types as the data submission requirement for the quality ASM performance category. However, not reporting all required measures would negatively affect an ASM's participant quality ASM performance category score as discussed in section III.C.2.(d).(i) of this final rule. Further, not meeting the data submission requirement for the quality ASM performance category would mean that an ASM participant would receive the maximum negative payment adjustment for the applicable ASM payment year as discussed in section III.C.2.f.(4) of this final rule. Setting the minimum data submission requirement as reporting more than one complete quality measure could penalize ASM participants that are unable to report required measures. We believe that the proposed minimum data submission requirement combined with the proposed scoring policies would provide the appropriate incentive for reporting all required quality measures while ensuring that we can appropriately evaluate quality performance.

We received public comments on our proposed data submission requirements for the quality ASM performance category. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support the proposed requirements for ASM low back pain participants to report on all the quality measures in the ASM low back pain cohort, noting that these requirements exceed those for MVP participants. The commenter also shared their belief that the measures have limited applicability to orthopedic surgeons.

Response: We appreciate the commenters for sharing their concern that ASM would require all low back pain participants to report on all low back pain quality measures. Although ASM's quality reporting requirements exceed those for MVPs, allowing participants to choose quality measures has historically led to overall high-quality scores within MIPS. Allowing ASM participants to select their quality measures would make it more difficult to meaningfully differentiate clinician performance. We disagree that the quality measures have limited applicability to orthopedic surgeons because we believe that orthopedic surgeons who are attributed 20 EBCMs provide longitudinal chronic condition care to beneficiaries with low back pain, which means it would be appropriate to hold them accountable for the low back pain quality measure set.

Comment: A commenter recommended that CMS should use eCQM quality measures in ASM whenever possible.

Response: We appreciate the commenters for stating their recommendation regarding interest in eCQM quality measures whenever possible. However, we disagree, because although we acknowledge the ease of reporting eCQMs, the CQMs selected for the quality measure sets better reflect ASM's goal to measure and incentivize improvement in the following three domains: (1) excess utilization, (2) evidence-based care and outcomes, and (3) patient-reported outcomes and experience.

Comment: A few commenters recommended that CMS provide additional clarification regarding the proposed requirements for the quality ASM performance category. A commenter expressed concern that the proposed rule does not clearly specify whether ASM participants must submit data for all ASM quality measures in their applicable cohort, or only for one quality measure (excluding administrative claims-based measures). Another commenter requested clarification on the exact number of quality measures clinicians are required to report on. Specifically, the commenter stated whether an ASM participant would need to contract with a third-party intermediary to report only the single MIPS CQM if their ASM cohort included three eCQMs and one MIPS CQM.

Response: We appreciate the commenters for their recommendation for further clarification regarding ASM quality measure reporting. As discussed in section III.C.2.e.(2).(b) of this final rule, for an ASM participant to receive a payment adjustment greater than the negative adjustment equal to the applicable ASM risk level (negative nine percent in the first two ASM payment years) they must meet the Quality ASM Performance Category Data Submission Requirement as discussed earlier in this section of this final rule. For an ASM participant to meet the quality ASM performance category data submission requirement, the ASM participant must report at least one required quality measure that is not an administrative claims-based collection type (discussed in sections III.C.2.d.(2).(b) and III.C.2.d.(2).(c) of this final rule) and meets the proposed data completeness requirement as discussed in section III.C.2.d.(2).(h).(i) of this final rule. Participants are still required to report all five measures in their quality set; however, if they do not meet the minimum case threshold as discussed in section III.C.2.d.(2).(h) they would not be scored on that measure, and that measure score would not be factored into the ASM participant's quality ASM performance category score as described in III.C.2.d.2.(i).(i) of this final rule. If a participant only reports three eCQMs and one MIPS CQM, they would be scored on those 4 measures but receive a zero for the measure for which they did not submit data, which means they would not meet the data completeness requirement for that measure.

After consideration of public comments, we are finalizing our provisions for data submission requirements for the quality ASM performance category as proposed at § 512.720(a)(1)(i).

(ii) *Improvement activities ASM performance category data submission requirements*

We proposed in § 512.720(a)(1)(ii) that the data submission requirement for the improvement activities ASM performance category would require that an ASM participant attest to completing or not completing the required ASM improvement activities defined in § 512.735. Unlike MIPS, we did not propose to include a "yes" attestation to the minimum data submission requirements to receive a final score under ASM as defined in § 512.745(b) as it would conflict with how we proposed to factor in the ASM improvement activities performance category score into the final score as proposed at § 512.745(a)(1)(iii).

We received public comments on our proposed data submission requirements for the improvement activities ASM performance category. The following is a summary of the comments we

received and our responses.

Comment: A few commenters did not support proposed data submission requirements for the improvement activities ASM performance category, noting the requirements as impractical and burdensome. Another commenter shared their concern that mandating two specific improvement activities for specialists could add significant burden for specialty practices already complying with other MIPS activities. The commenter recommended that CMS align the ASM improvement activities category with MIPS to allow greater flexibility and choice during the initial ASM performance years.

Response: We appreciate commenters for sharing their concerns regarding the data submission requirements for the improvement activities ASM performance category. We recognize that introducing two ASM-specific mandatory improvement activities may be burdensome for specialty practices that may participate as a group in MIPS. However, we believe that these ASM-specific improvement activities are important to incentivizing practice transformation and improved specialist-PCP integration to improve chronic condition management. We refer readers to section III.C.2.d.(4) of this final rule for additional discussion on the basis for our improvement activities

After consideration of public comments, we are finalizing our provisions for data submission requirements for the improvement activities ASM performance category as proposed at § 512.720(a)(1)(ii).

(iii) *Promoting Interoperability ASM performance category data submission requirements*

The proposed requirements for the Promoting Interoperability ASM performance category at § 512.720(a)(1)(iii) align with the MIPS requirements as defined at § 414.1325(1)(iii).

We did not receive any public comments on our proposed Promoting Interoperability data submission requirements and are, therefore, finalizing the provisions as proposed at § 512.720(a)(1)(iii).

(iv) *ASM performance categories without data submission requirements*

Like the cost performance category or administrative claims-based quality measures under MIPS, we proposed at § 512.720(a)(2) that there would be no data submission requirements for the cost ASM performance category or for quality measures that have an administrative claims-based collection type. Like MIPS, performance in the ASM cost performance category and on some quality, measures would be calculated using administrative claims data, which includes claims submitted with dates of service during

the applicable ASM performance year that are processed no later than 60 days following the close of the applicable ASM performance year.

We did not receive any public comments on our proposed provisions related to ASM performance categories without data submissions requirements and are, therefore, finalizing the provisions as proposed at § 512.720(a)(2).

(v) *Data submission types*

We proposed at §§ 512.720(b)(1) and (2) that an ASM participant would, like an individual MIPS eligible clinician, be able to submit their ASM data using, for the quality ASM performance category, the direct, login and upload, submission types, and for improvement activities or Promoting Interoperability ASM performance categories, the direct, login and upload, or login and attest submission types as proposed at § 512.720(b). These are the same submission types available under MIPS.

We received public comments on our proposed data submission types. The following is a summary of the comments received and our responses.

Comment: A commenter supported the proposal to align ASM data submission types— including direct, log in and upload, and the use of third-party intermediaries, with the existing MIPS framework. The commenter shared their belief that alignment between ASM and MIPS data submission types would reduce confusion, limit the administrative burden on clinicians, and leverage a familiar infrastructure.

Response: We appreciate the commenters for their support of the ASM proposal to align ASM data submission types with the existing framework in MIPS leading to lower administrative burden on clinicians.

Like the policy established under MIPS, we proposed at § 512.720(c) that ASM participants would be permitted to submit their ASM data using multiple submission types for any ASM performance category described at § 512.720(b) as applicable; provided, however, that the ASM participant uses the same identifier for all ASM performance categories and all data submissions.

We did not receive any comments on our proposed provisions related permitting ASM participants to submit data using multiple submission types for any ASM performance category as applicable.

After consideration of public comments, we are finalizing our proposed provisions for data submission types as proposed at §§ 512.720(b)(1) and (2). We are also finalizing our proposed provisions on multiple submission types as applicable for each ASM performance category as proposed at § 512.720(c).

(vi) *Data submission deadline*

We proposed at § 512.720(d) that ASM participants would need to submit all required data and attestations as required for each ASM performance category by March 31 following the close of the applicable ASM performance year, or a later date as specified by CMS. This proposal aligns with the deadline policy established under MIPS at § 414.325(e). We considered requiring a data submission deadline earlier than March 31 but believed that it would not provide ASM participants with sufficient time to prepare their data submission.

We received public comments on our proposed data submission deadline. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support the proposed data submission deadline of March 31 following the close of the applicable ASM performance year, noting concerns with meeting the deadline due to the complex reporting requirements across multiple programs, and recommended extending the ASM data submission deadline to the end of April.

Response: We appreciate the commenters for sharing their concerns regarding our data submission deadline. However, ASM's data submission deadline aligns with the deadline in MIPS specified at § 414.325(e).

Comment: A commenter supported the proposed data submission deadline of March 31 following the close of the applicable ASM performance year, noting its alignment with traditional MIPS and MVP deadlines could decrease burden on ASM participants.

Response: We appreciate the commenter for their support of our data submission deadlines and agree that alignment with MIPS and MVP deadlines decreases reporting burdens.

After consideration of public comments, we are finalizing our proposed data submission deadline as proposed at § 512.720(d).

(vii) *Treatment of multiple data submissions*

Like the policy established under MIPS, for multiple data submissions received in the quality and improvement activities ASM performance categories, for an ASM participant submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), we proposed at § 512.720(e) to calculate and score each submission received and assign the highest of the scores. We proposed at § 512.720(e)(1) that for multiple data submissions received for an individual ASM participant from one or multiple submitters in the same organization, we proposed to score the most recent submission. We proposed at § 512.720(e)(2), that for multiple data submissions received for the Promoting Interoperability performance category, we would calculate a score for each data submission received and assign the highest of the scores.

We received public comments on our proposed provisions for the treatment of multiple data submissions. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed approach for multiple ASM data submissions. The commenters noted the proposed policy would allow an ASM participant to be scored on the data submission or measure with the greatest number of achievement points, aligned with MIPS and could help reduce confusion among clinicians and administrative staff during reporting.

Response: We appreciate the commenters for their support of our approach towards scoring multiple ASM data submissions and believe that our policy rewards participants for earned ASM performance achievement points.

After consideration of public comments, we are finalizing our proposed provisions related to multiple data submission types as proposed at § 512.720(e).

(2) Quality ASM Performance Category

The quality ASM performance category supports the model goals of improving quality of care with a focus on measures that are relevant to ASM clinical specialties and targeted chronic conditions. It also seeks to decrease the cost of care for beneficiaries with ASM-targeted chronic conditions. Measuring quality of care helps identify areas for improvement and ensures that clinical interventions are effective and lead to improved patient outcomes. The importance of the quality ASM performance category is reflected in the weight of the performance category on the final score, discussed in section III.C.2.e.(1) of this final rule.

(a) Background

We proposed at § 512.725(b) and (c) to use a quality measure set specific to each ASM cohort, one measure set for heart failure (HF) and one measure set for low back pain (LBP), which would contain condition-specific mandatory measures. Each ASM participant must report all finalized measures specified in Table B-D4 for their applicable chronic condition, except for the proposed administrative claims-based measures, which would be calculated by CMS based on their submitted claims. These measures would likely stay consistent throughout the duration of the model to support reporting continuity, minimize burden, and ensure a reliable and valid model evaluation. The quality measurement approach in ASM is similar to the MVP reporting option under MIPS in that it limits reporting to a subset of clinically relevant measures. However, while the MVP reporting option allows a clinician to select an MVP and choose which MVP measures to report, the ASM participant would be required to report all quality measures in their respective ASM measure set.

Medicare's payment landscape is continuing to transform, moving away from traditional FFS payments that are not tied to quality and towards value-based models with increased provider accountability. ASM is a continuation of these efforts, strengthening the connection between quality and payment. We aim, in payment models such as ASM, to utilize quality measures that incentivize evidence-based care and prevention, improve patient outcomes, and reduce low-value health care spending.

We proposed to avoid making significant changes to these measure sets over the period of model; however, we may propose to add or remove measures through notice-and-comment rulemaking if we believe refinements to the measure set are necessary. We may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. We would use notice-and-comment rulemaking to propose any modifications, such as adding or removing measures for monitoring quality or calculating scores for quality performance. We sought comment on this proposal.

ASM is designed to provide financial incentives for measurable improvements in clinical outcomes for beneficiaries. We expect our quality measurement strategy to increase adherence to clinical guidelines, focus attention on outcomes to reduce costs, and enhance the patient experience. Several of the finalized measures also promote prevention, as detailed in Table B-D4, by mitigating the progression

of the chronic diseases that ASM targets and reducing the risk for other comorbid diseases that may exacerbate health issues. Each quality measure contains measures that aim to measure and incentivize improvement in the following three domains: (1) excess utilization, (2) evidence-based care and outcomes, and (3) patient-reported outcomes and experience. Each measure set would include a utilization-focused measure to assess appropriate use of select services in chronic disease management. This measurement area may also indicate where excess or inappropriate utilization is occurring, which aligns with CMS priorities to reduce spending related to unnecessary care, imaging, or procedures. Measures in the evidence-based care and outcomes domain are clinically relevant to the conditions of focus, can meaningfully discern differences in care furnished by ASM participants, and are associated with improved outcomes for patients. Finally, measures related to patient-reported outcomes capture what matters most to patients, and incentivizing ASM participants to be more attuned to the patient experience could drive improvements in functional status among beneficiaries receiving treatment for heart failure and low back pain. We believe that the measures in all three domains are clinically relevant to the conditions of focus and would align with other CMS programs and nationwide measurement efforts.

TABLE B-D4: ASM MEASURE SETS FOR THE ASM QUALITY PERFORMANCE CATEGORY

Domain	Prevention Category	Measure	Collection Type(s)
Heart Failure			
Excess Utilization	Adverse events and acute care utilization	Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with HF (MIPS Q492) with modification	Claims
Evidence-based Care and Outcomes	Reduction of disease progression	HF: Beta-Blocker Therapy for LVSD (MIPS Q008)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Reduction of disease progression	HF: ACE Inhibitor or ARB or ARNI Therapy for LVSD (MIPS Q005)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Reduction of disease progression	Controlling High Blood Pressure (MIPS Q236)	eCQM MIPS CQM
Patient Reported Outcomes and Experience	Function/health status/wellbeing	Functional Status Assessments for Heart Failure (MIPS Q377)	eCQM
Low Back Pain			
Evidence-based Care and Outcomes	Adverse events and acute utilization	Use of High-Risk Medications in Older Adults (MIPS Q238)	eCQM MIPS CQM

Evidence-based Care and Outcomes	Risk reduction/absence of disease	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134)	eCQM MIPS CQM
Evidence-based Care and Outcomes	Risk reduction/absence of disease	Preventive Care and Screening: BMI Screening and Follow-Up Plan (MIPS Q128)	eCQM MIPS CQM
Patient Reported Outcomes and Experience	Function/health status/wellbeing	Functional Status Change for Patients with Low Back Impairments (MIPS Q220)	MIPS CQM
Excess Utilization	To Be Determined	To Be Determined in CY 27 Rulemaking	Claims

(i) Performance Year for the Quality ASM Performance Category

We proposed at § 512.725(a) that the ASM performance year for quality measures would be the full calendar year from January 1 to December 31, and the performance year would occur 2 years prior to an applicable ASM payment year. We believe that setting the ASM performance year for quality measures in this way aligns with MIPS as defined at § 414.1320 and would be easily adoptable for ASM participants.

We solicited comments on our proposed approach setting the ASM performance year for quality measures.

We did not receive public comments on this provision, and therefore, we are finalizing the proposed ASM performance year for quality measures as proposed at § 512.725(a).

(b) Quality Measure Set for the ASM Heart Failure Cohort

We proposed at § 512.725(b)(1) through (5) to include the following measures in the heart failure quality measure set. Each ASM heart failure participant must report each finalized measure using one of the collection types specified in Table B-D4.

(i) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure (HF) (MIPS Q492)

We proposed to include Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure (HF) (MIPS Q492) in the ASM heart failure quality measure set. By assessing potentially preventable cardiovascular-related hospital admissions, this measure incentivizes clinicians to adopt evidence-based practices in heart failure management, improve care coordination, and enhance the overall quality of care.

A hospital readmission, for any reason, is disruptive to patients and caregivers, costly to the health care system, and puts patients at additional risk of hospital-acquired infections and complications.[184] Readmissions are also a major source of patient and family stress and may contribute substantially to a decline in functional ability, particularly in older patients.[185] Some readmissions are unavoidable and result from inevitable progression of disease or worsening of chronic conditions. Patients with heart failure, particularly those at a more advanced stage, are vulnerable to a range of factors that may increase their risk for cardiovascular-related hospitalizations.[186] risk of hospitalization may be related to an individual's clinical and social/community risk factors but may also be affected by the quality of care received. Activities that could improve quality of care include the adoption of guideline-directed medical therapy, early intervention for acute symptoms, optimal care coordination across providers, and support for self-management. Policy changes, such as the Medicare Hospital Readmissions Reduction Program, have led to a decrease in readmission rates for both principal and secondary heart failure hospitalizations; however, readmission rates in both groups remain high.[187] We proposed to include this measure to continue the momentum on reducing avoidable hospital admissions and readmissions, as well as improve overall quality of care for Medicare patients with heart failure.

In addition, this measure aligns with other quality programs, such as the Quality Payment Program, which includes the measure in the Advancing Care for Heart Disease MVP. Another benefit of the measure is that it is calculated using administrative claims, which reduces reporting burden for the ASM participant.

Furthermore, ASM proposed to use this measure at the TIN/NPI level. We pursued additional testing and analyses to ensure measure validity at this level. To date, this measure has been validated at the TIN level in the MIPS program. Analyses have determined a certain threshold of attributed patients' needs to be met to ensure measure validity; this threshold can be challenging to achieve at the TIN/NPI level in MIPS given the wide range of specialty types that participate. Internal analyses indicate that, given the 20 EBCM episode threshold for participation of cardiologists described in section

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[184]Dhaliwal JS, Dang AK. Reducing Hospital Readmissions. Nih.gov. Published June 7, 2024. https://www.ncbi.nlm.nih.gov/books/NBK606114/
[185]Dhaliwal JS, Dang AK. Reducing Hospital Readmissions. Nih.gov. Published June 7, 2024. https://www.ncbi.nlm.nih.gov/books/NBK606114/
[186] Malhotra C, Chaudhry I, Yeo Khung Keong, Sim D. Multifactorial risk factors for hospital readmissions among patients with symptoms of advanced heart failure. *ESC heart failure*. 2024;11(2):1144-1152. doi:https://doi.org/10.1002/ehf2.14670
[187] Blecker S, Herrin J, Li L, Yu H, Grady JN, Horwitz LI. Trends in Hospital Readmission of Medicare-Covered Patients With Heart Failure. *Journal of the American College of Cardiology*. 2019;73(9):1004-1012. doi:https://doi.org/10.1016/j.jacc.2018.12.040.

III.C.2.c.(3)(b) of this final rule, meeting this threshold of attributed patients in ASM would not be a significant issue or threat to measure validity. For that reason, we anticipate this measure would be valid and reliable at the TIN/NPI level for ASM participants treating heart failure.

We solicited comment on the proposal to include the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with HF (MIPS Q492) measure in ASM and to assess performance at the TIN/NPI level.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed inclusion of MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure measure in the ASM heart failure quality measure set. The commenters shared their belief that the inclusion of this measure would promote care coordination and enhance patient outcomes and quality of care. A commenter supported expanding the focus beyond a 30-day hospital readmission measure to emphasize the importance of long-term, chronic care needed for heart failure patients.

Response: We appreciate commenters' support of the proposed inclusion of MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure measure in the ASM heart failure quality measure set. We agree that this is an important measure to promote accountability in care coordination and enhance patient outcomes. We also appreciate the feedback regarding the importance of expanding focus beyond 30-day readmission measures to emphasize long-term, chronic care management for heart failure patients.

Comment: A few commenters did not support the proposed inclusion of MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure measure in the ASM heart failure quality measure set, noting that the majority of readmissions are not preventable through heart failure management. A commenter cited research indicating that only 17 to 35 percent of readmissions are attributed to heart failure re-exacerbation, and therefore, the commenter expressed concern that holding general cardiologists engaged in longitudinal care for heart failure patients accountable for total cardiovascular admission rates may unfairly penalize these clinicians for outcomes beyond their clinical control. A commenter requested clarification on how the measure would interact

with the heart failure EBCM, to ensure clinicians are not subject to overlapping penalties for the same utilization events across quality and cost domains.

Response: We appreciate the feedback regarding concerns about the proposed inclusion of MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure measure. The measure methodology has several mechanisms to account for situations when admissions are outside the control of providers, such as exclusion criteria for very ill or complicated patients, identification of planned admissions, a 10-day buffer period following discharge, and a risk adjustment model that includes demographic, clinical, and social risk factors. We believe these are appropriate safeguards that address the concerns raised about penalizing providers for outcomes beyond their clinical control. Additionally, the measure focuses specifically on admissions that are cardiovascular in nature, addressing the concern that providers may be penalized for admissions completely unrelated to heart failure care. A key goal of ASM is to promote enhanced accountability for longitudinal care by providers for their patients, and this measure complements the heart failure EBCM to ensure accountability as they measure different aspects of care. We do not perceive this as overlapping penalties, as they are different metrics and the cost of a heart failure episode is not encapsulated in unplanned admissions alone.

Comment: A few commenters did not support the proposal to apply the MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure measure at the TIN/NPI level, noting that this measure was not designed to assess individual clinicians and has only been in used in MIPS for evaluating groups. A few commenters also noted that the measure's reliability has only been tested at the group level, not at the individual clinician or TIN/NPI level, and reliability scores decrease for groups with fewer heart failure patients. A commenter shared their concern that clinicians may have limited time to implement the measure, since CMS noted the measure's revised specifications would be released in the rule. Another commenter expressed concern that attributing this measure at the TIN/NPI level, particularly for specialists working in team-based settings, could misrepresent individual accountability for admissions influenced by broader social risk factors or primary care coordination. The commenters recommended that CMS monitor for unintended disparities and ensure risk adjustment methodologies account for factors outside of cardiologists' direct control.

Response: We appreciate the feedback regarding the application of MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients With Heart Failure at the TIN/NPI level. Internal analyses identified that an overwhelming majority of likely heart failure ASM participants would individually meet or exceed the case minimum of 21 for this measure, which is the volume threshold used in other CMS programs. The analysis used the measure specification to simulate a performance year for providers that met the ASM participant inclusion criteria, demonstrating feasibility for implementation at the individual clinician (TIN/NPI) level.

To address concerns about attribution and accountability, ASM will slightly modify the measure specifications to attribute solely to ASM participants who have had 1 or more visits with the beneficiary. Focusing the measure in this way allows ASM participants to be accountable for the health of patients they have actively treated, while addressing concerns about misrepresenting individual accountability in team-based settings. We will release more technical details in the future in a form and manner determined by CMS.

We recognize the concerns about social risk factors and coordination issues beyond cardiologists' direct control, and we will continue to monitor unintended disparities while ensuring that risk adjustment methodologies appropriately account for factors outside of specialists' direct influence. The measure's established risk adjustment framework, combined with our attribution modifications, should help address these concerns while maintaining meaningful quality assessment.

After consideration of public comments, we are finalizing the inclusion of the MIPS Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure measure in the heart failure quality measure set as proposed as § 512.725(b)(1).

(ii) Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008)

We proposed to include Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008) in the ASM heart failure quality measure set. This measure aims to promote the appropriate use of beta-blocker therapy in select patients with heart failure with reduced ejection fraction (HFrEF). It assesses the percentage of patients aged 18 years and older with a diagnosis of heart failure with a current or prior left ventricular ejection fraction (LVEF) ≤ 40 percent who were

prescribed beta-blocker therapy either within a 12-month period of being seen in the outpatient setting or at each hospital discharge. Beta-blockers, especially when delivered as part of guideline-directed medical therapy, decrease the risk of major cardiovascular events, reduce mortality and hospitalization in patients with HFrEF, lessen the symptoms of heart failure, improve the clinical status of these patients, and reduce future clinical deterioration associated with heart failure.[188] These improvements are observed in all populations with heart failure of various etiologies, such as patients with or without coronary artery disease (CAD), patients with or without diabetes, older patients, as well as women and across various racial and ethnic groups.[189]

Despite its survival benefits, use of beta blockers in eligible patients remains suboptimal.[190,191] Nonadherence to medications prescribed for heart failure, including beta-blockers, can be associated with adverse outcomes such as hospital readmission and mortality.[192,193] By including this measure, we aim to increase the appropriate use of beta-blocker therapy in eligible patients with heart failure. This aligns with the goals of ASM to drive improvements in the quality of care delivered to heart failure patients, particularly in evidence-based pharmacotherapy. In addition, inclusion of this measure aligns with other quality programs, such as the Quality Payment Program, which includes the measure in the Advancing Care for Heart Disease MVP, and the Cardiology Core Quality Measures Collaborative (CQMC) set. We sought comment on the proposal to include Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008) in the ASM heart failure quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

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[188] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063

[189] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063

[190] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063

[191] Kim SE, Byung Su Yoo. Treatment Strategies of Improving Quality of Care in Patients With Heart Failure. *Korean circulation journal*. 2023;53. doi:https://doi.org/10.4070/kcj.2023.0024

[192] Ruppar TM, Cooper PS, Mehr DR, Delgado JM, Dunbar-Jacob JM. Medication Adherence Interventions Improve Heart Failure Mortality and Readmission Rates: Systematic Review and Meta-Analysis of Controlled Trials. *Journal of the American Heart Association*. 2016;5(6). doi:https://doi.org/10.1161/jaha.115.002606

[193] Ho PM, Magid DJ, Shetterly SM, et al. Medication nonadherence is associated with a broad range of adverse outcomes in patients with coronary artery disease. *American Heart Journal*. 2008;155(4):772-779. doi:https://doi.org/10.1016/j.ahj.2007.12.011.

Comment: A few commenters supported the proposal to include the MIPS Q008 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) measure in the ASM heart failure measure set. A commenter noted that this measure would help address the under-prescription of evidence-based therapies and promote the appropriate use of combination or quadruple therapy, which includes beta-blocker therapy, in patients with HFrEF.

Response: We appreciate the commenters' supportive feedback regarding the inclusion of MIPS Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) in the ASM heart failure measure set. We agree that this measure is essential for encouraging the adoption of comprehensive, evidence-based treatment approaches that have been shown to improve outcomes for heart failure patients. The measure aligns with current clinical guidelines that emphasize the importance of optimizing medical therapy, including the use of combination or quadruple therapy regimens that incorporate beta-blockers as a cornerstone of HFrEF management.

Comment: A few commenters expressed concern regarding the proposal to include the MIPS Q008 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) measure in the ASM heart failure quality measure set, noting that the measure is topped out in MIPS. The commenters recommended that CMS consider alternative quality measures, that are not topped out, for inclusion in the ASM measure set. A few commenters specifically noted that the measure only applies to patients with reduced ejection fraction and excludes those with preserved ejection fraction. A commenter recommended that CMS consider respecifying this measure as an outcomes-based measure. Another commenter recommended that CMS ensure necessary exclusions for clinically justified cases, noting that some patients with left ventricular systolic dysfunction may have contraindications to beta-blocker therapy.

Response: We appreciate the comments regarding the proposed inclusion of MIPS Q008 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) measure in the ASM heart failure quality measure set. While we are aware that the measure may be topped out in the MIPS program, we believe that the required reporting structure in ASM may yield different results than those seen in MIPS, where providers have flexibility in measure selection. We carefully considered several measures and selected those that are most clinically relevant and methodologically valid, though

we acknowledge we are limited by existing measures and cannot develop outcome measures for every clinical scenario. We believe this measure set provides an adequate assessment of patient care quality related to heart failure. This measure is clinically valid and reliable, incorporating necessary exclusions for beta-blocker therapy when clinically documented reasons exist (for example, low blood pressure, fluid overload, asthma, recent intravenous positive inotropic agent treatment, allergies, intolerances, other medical reasons, patient refusal, or other patient-specific factors). While the measure may not apply to a cardiologist's entire patient panel, it remains a valid assessment tool for the significant portion of heart failure patients that cardiologists treat with reduced ejection fraction.

After consideration of public comments, we are finalizing the inclusion of the (MIPS Q008) HF: Beta-Blocker Therapy for LVSD in the heart failure quality measure set as proposed at § 512.725(b)(2).

(iii) Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005)

We proposed to include Heart Failure (HF): Angiotensin-Converting Enzyme (ACEi) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005) in the heart failure quality measure set. This measure assesses the appropriate use of the specified medicines in patients with heart failure with reduced LVEF. Adherence to this class of medications, especially as part of guideline-directed medical therapy, offers cardioprotective benefits in patients with heart failure and reduces mortality and heart failure-related hospitalizations.[194,195] Furthermore, McMurray et al. in PARADIGM-HF showed use of angiotensin receptor–neprilysin inhibitor compared to enalapril, an ACEi, not only reduced risk for cardiovascular death and hospitalization related to heart failure, but also decreased the symptoms and physical limitations of heart failure.[196] Similar to beta blockers, optimal dosing and adherence to this group of medication in heart failure patients remains suboptimal.[197] By including this measure, we can

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[194] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063

[195] Düsing R. Mega clinical trials which have shaped the RAS intervention clinical practice. *Therapeutic Advances in Cardiovascular Disease*. 2016;10(3):133-150. doi:https://doi.org/10.1177/1753944716644131

[196] McMurray JJV, Packer M, Desai AS, et al. Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. *New England Journal of Medicine*. 2014;371(11):993-1004. doi:https://doi.org/10.1056/nejmoa1409077

[197] Kim SE, Byung Su Yoo. Treatment Strategies of Improving Quality of Care in Patients With Heart Failure. *Korean circulation journal*. 2023;53. doi:https://doi.org/10.4070/kcj.2023.0024

incentivize cardiologists participating in ASM to prescribe evidence-based pharmacotherapy for patients with HFrEF. In addition, inclusion of this measure aligns with other quality measurement efforts, such as the Advancing Care for Heart Disease MVP in the Quality Payment Program and the Cardiology Core Quality Measures Collaborative (CQMC) set. We sought comment on the appropriateness of including this measure in the heart failure quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern about including the MIPS Q005: ACE Inhibitor or ARB or ARNI Therapy for LVSD in the ASM heart failure measure set, noting that the measure is topped out in MIPS. The commenters recommended that CMS consider alternative quality measures for inclusion in ASM that have not reached topped-out status. A commenter specifically noted that the measure steward would discontinue supporting the measure starting in CY 2027. Another commenter expressed concern that patients with left ventricular systolic dysfunction may have contraindications to ACEi/ARB/ARNI therapy and recommended that CMS include necessary exclusions for clinically justified cases.

Response: We appreciate the commenters' feedback regarding the inclusion of MIPS Q005: ACE Inhibitor or ARB or ARNI Therapy for LVSD in the ASM heart failure measure set. While we acknowledge that this measure may be topped out in the MIPS program, we believe that the required reporting structure in ASM may yield different results than those seen in MIPS, where providers have flexibility in measure selection.

We also believe this remains a valuable measure to include despite the measure steward's announcement that they will no longer maintain it in the future. The steward did not suggest measure alternatives, and there are no suitable substitutes that would be as impactful in our heart failure quality measure set. The steward's primary rationale for discontinuing maintenance was the topped-out status; however, as stated, we do not believe this will be the case given the mandatory nature of measures in our model.

Regarding concerns that patients with left ventricular systolic dysfunction may have contraindications to ACEi/ARB/ARNI therapy, the measure addresses this through multiple built-in

mechanisms. The measure includes denominator exclusions for clinically justified cases, such as patients with LVADs, documented medical reasons for not prescribing these medications, hypotensive patients at risk of cardiogenic shock, hospitalized patients with marked azotemia, and those with allergies, intolerances, or other medical contraindications. Additionally, patients who have declined therapy are excluded. These exclusions ensure that clinically justified cases are appropriately addressed, as the commenters recommended.

Comment: A commenter recommended that CMS consider a composite adherence measure or a PRO-PM linked measure to better capture the value of guideline-directed medical therapy in practice.

Response: We appreciate this comment regarding the use of composite adherence measures or patient-reported outcome process measures (PRO-PM) linked measures to better capture the value of guideline-directed medical therapy in practice. Our current ACE inhibitor/ARB/ARNI and beta-blocker measures are the best existing tools we have to promote guideline-directed medical therapy (GDMT) for heart failure patients. While we will continue to review whether other measures are developed in the future, we believe these measures are appropriate for assessing quality of care and incentivizing optimization of these therapies. We do include a patient-reported outcome process measure related to functional status, which serves as a complementary tool to determine quality of care and provides additional insight into patient outcomes.

Comment: A commenter supported the proposed inclusion of MIPS Q005: ACE Inhibitor or ARB or ARNI Therapy for LVSD in the ASM heart failure measure set, noting that the appropriate use of these therapies is associated with reductions in mortality and hospitalizations related to heart failure.

Response: We appreciate the commenter for their support of the proposed inclusion of MIPS Q005: ACE Inhibitor or ARB or ARNI Therapy for LVSD in the ASM heart failure measure set. We agree that the appropriate use of these evidence-based therapies is critical for improving patient outcomes in heart failure management. The clinical evidence demonstrates that ACE inhibitors, ARBs, and ARNIs are associated with significant reductions in mortality and hospitalizations for patients with left ventricular systolic dysfunction. Including this measure in the ASM heart failure measure set aligns with our commitment to promoting the use of guideline-directed medical therapy that has proven benefits for patients with heart failure.

Comment: A commenter supported the proposed inclusion of MIPS Q005: ACE Inhibitor or ARB or ARNI Therapy for LVSD in the ASM heart failure measure set and recommended that CMS consider broadening the measure to account for a wider range of future innovations or related therapies that may enter the market. The commenter further recommended that CMS establish higher standards for adherence to oral antihypertensive therapies within the model to address issues related to suboptimal dosing and medication adherence.

Response: We appreciate the support of the proposed inclusion of MIPS Q005: ACE Inhibitor or ARB or ARNI Therapy for LVSD in the ASM heart failure measure set. We appreciate the recommendation to consider broadening the measure to account for future innovations and related therapies that may enter the market. We will assess the measure set regularly to account for changes in clinical guidelines and medication therapies and innovations in care which could impact the model, and the measures included. Regarding the recommendation for higher standards for adherence to oral antihypertensive therapies, we believe this measure and the beta-blocker measure appropriately assess adherence to antihypertensive therapies and should promote improvements in medication management. We recognize that suboptimal dosing and medication adherence are important challenges in heart failure management, and these measures are designed to encourage providers to focus on evidence-based prescribing practices. The combination of these measures within the quality measure set will help drive quality improvements in heart failure care while maintaining flexibility to adapt to evolving clinical standards.

After consideration of public comments, we are finalizing the inclusion of the (MIPS Q005) HF: ACE Inhibitor or ARB or ARNI Therapy for LVSD measure in the heart failure quality measure set as proposed at § 512.725(b)(3).

(iv) Controlling High Blood Pressure (MIPS Q236)

We proposed including Controlling High Blood Pressure (MIPS Q236) in the heart failure quality measure set for ASM because optimal blood pressure management is a critical part of heart failure

management and uncontrolled blood pressure can contribute to complications and progression.[198,199] For example, severe hypertension can result in pulmonary edema (more common in patients with preserved LVEF), requiring urgent treatment to reduce blood pressure.[200] Controlling blood pressure helps reduce the risk of adverse outcomes, such as hospitalizations and mortality related to heart failure.[201,202] By including this measure, ASM incentivizes cardiologists to optimize blood pressure control, particularly given that patients with heart failure very commonly have a history of hypertension.[203] In addition, this measure complements the two other quality measures for heart failure in ASM, as the use of beta blockers and ACEi/ARB/ARNIs also have favorable effects on heart failure outcomes and lower blood pressure.[204] The complimentary emphasis on blood pressure control and medication management in this measure set may also slow disease progression and function as a form of tertiary prevention in heart failure patients. Furthermore, its inclusion in other quality measure sets, such as the CMS Universal Foundation Measure Set and the Cardiology Core Quality Measures Collaborative (CQMC) set has resulted in more widespread adoption, helping streamline reporting and reduce burden.[205] We sought comment on our inclusion of this measure in the heart failure quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposed inclusion of MIPS Q236: Controlling High Blood Pressure in the ASM heart failure quality measure set. A commenter expressed concern that using a single, most recent blood pressure reading to determine a patient's blood pressure control does not align with clinical guidelines or best practices in hypertension management, which recommend longitudinal assessment of blood pressure to appropriately reflect a patient's status. A commenter noted

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[198] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063

[199] Oh GC, Cho HJ. Blood pressure and heart failure. *Clinical Hypertension*. 2020;26(1). doi:https://doi.org/10.1186/s40885-019-0132-x.

[200] Ratko Lasica, Lazar Djukanovic, Jovanka Vukmirovic, et al. Clinical Review of Hypertensive Acute Heart Failure. *Medicina (Kaunas Spausdinta)*. 2024;60(1):133-133. doi:https://doi.org/10.3390/medicina60010133.

[201] The SPRINT Research Group. A Randomized Trial of Intensive versus Standard Blood-Pressure Control. *New England Journal of Medicine*. 2015;373(22):2103-2116. doi:https://doi.org/10.1056/nejmoa1511939.

[202] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063.

[203] Messerli FH, Rimoldi SF, Bangalore S. The Transition From Hypertension to Heart Failure. *JACC: Heart Failure*. 2017;5(8):543-551. doi:https://doi.org/10.1016/j.jchf.2017.04.012.

[204] Oh GC, Cho HJ. Blood pressure and heart failure. *Clinical Hypertension*. 2020;26(1). doi:https://doi.org/10.1186/s40885-019-0132-x.

[205] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS — The Universal Foundation. *New England Journal of Medicine*. 2023;388(9). doi:https://doi.org/10.1056/nejmp2215539.

that the measure should be revised to incorporate multiple blood pressure readings or longitudinal data before including in the ASM heart failure quality measure set.

Response: We appreciate the feedback regarding the inclusion of MIPS Q236: Controlling High Blood Pressure in the ASM heart failure quality measure set. The commenters' concerns about using a single, most recent blood pressure reading versus longitudinal assessment could be provided as feedback to the measure steward for future consideration. Currently, we believe that MIPS Q236 is the best measure available to ensure this vital activity occurs in heart failure care. Using this measure allows us to align with MIPS and other quality reporting programs, thereby reducing the administrative burden on ASM participants. While we acknowledge that clinical guidelines recommend longitudinal assessment of blood pressure, the current measure specification represents the most feasible approach for standardized quality measurement across CMS programs. We will continue to monitor developments in blood pressure quality measures and consider updates as improved measures become available through established measure development processes.

Comment: A commenter expressed concern that ASM participants may lack vendor support for reporting the measure, leading to increased costs and burden for clinicians. Another commenter recommended that CMS should provide credit to clinicians for evidence-based interventions, such as dietary advice or diuretics, even if blood pressure control is not achieved, since blood pressure control may not be fully within a clinician's influence.

Response: We acknowledge the potential burden that participants may face regarding vendor support for reporting measures, but we believe this is an important measure for our heart failure quality measure set. This measure has been part of the MIPS program since CY 2018, providing ample time for vendors and systems to adopt it. This measure’s importance has also been signaled as important and relevant with its inclusion in the CMS Universal Foundation of Quality Measures. Participants have until 2027 to ensure that they can report this measure, which we believe provides enough advance notice to ensure those pursuing reporting can do so successfully. Also, we believe that the performance assessment structure of ASM will incentivize evidence-based interventions such as dietary advice and diuretic management. While there are no specific measures for these individual activities, our improvement activities complement whole person health activities such as diet counseling and screening for health-

related social needs (HRSNs). We believe that participants who choose to provide these evidence-based interventions to their patients will see improved performance in ASM, thereby incentivizing these activities.

Comment: A few commenters supported the proposed measure, MIPS Q236: Controlling High Blood Pressure, because blood pressure management is a critical part of managing heart failure. A commenter stated that the measure is part of the Universal Foundation measure set, and thus including this measure in ASM will promote alignment across programs. A commenter supported the measure but suggested that CMS consider recommended pharmacological interventions to help control high blood pressure, such as loop diuretics. Another commenter recommended that CMS consider incorporating measures that assess sustained improvements in blood pressure. Finally, given the recent release of updated blood pressure guidelines, a commenter noted that CMS may have to modify this measure in the near future to reduce the current target blood pressure range which may result in limited comparability of results over the 5-year proposed timeframe.

Response: We appreciate the comments regarding the proposed inclusion of MIPS Q236: Controlling High Blood Pressure in the ASM heart failure quality measure set. We agree that blood pressure management is a critical component of heart failure care, and we believe that measuring this will promote clinical improvements by providers, such as implementing recommended pharmaceutical interventions like loop diuretics as suggested. We recognize the value of alignment across CMS programs, and including this Universal Foundation measure in ASM supports that goal. We are limited as there are not valid and reliable measures established for all clinical scenarios, and therefore, we must use the measures that are available to us. We believe this measure is an appropriate, clinically valid, and widely used measure for assessing blood pressure control. Regarding the recommendation for measures that assess sustained improvements in blood pressure, we will consider this feedback as we continue to evaluate the measure set. We will continue to review the latest guidelines in clinical care for heart failure, and the specifications of this measure could be adjusted in the future by the measure steward depending on research developments and updated clinical guidelines, including the recent blood pressure guideline updates mentioned. We acknowledge that modifications to align with updated guidelines may impact comparability over time, which is why we do not plan to make changes to the measure set over time, but

ensuring clinical relevance and adherence to current evidence-based standards remains our priority.

Comment: A few commenters offered other recommendations to CMS on the proposed measure, MIPS Q236: Controlling High Blood Pressure. A commenter recommended updating the measure with risk stratification or digital quality components to address disparities, workflow issues, and patient non-compliance. The commenter also recommended that CMS consider accepting home or remote blood pressure readings. Finally, the commenter requested clarification regarding whether a missed reading due to a single skipped visit or lack of patient engagement would disproportionately impact performance scores under ASM. Additionally, a few commenters noted that pharmacists and registered dietitian nutritionists can play an important role in controlling blood pressure under the measure and therefore recommended that CMS include pharmacists and registered dietitian nutritionists in ASM.

Response: We appreciate the commenters' feedback regarding MIPS Q236: Controlling High Blood Pressure and the recommendations for measure enhancements. We aim to align with the specifications determined by the measure steward to ensure we do not create undue burden by changing specifications across different programs. For recommendations regarding risk stratification, digital quality components, acceptance of home or remote blood pressure readings, and other measure specification changes, we recommend directly contacting the measure steward directly to suggest these modifications. We will not include pharmacists or registered dietitian nutritionists as eligible participants in ASM, but to perform well on this and other measures, ASM participants may partner with or leverage these valuable healthcare resources as part of their care delivery approach. This collaborative approach allows ASM participants to benefit from the expertise of pharmacists and dietitians in managing hypertension while maintaining the model's focus on specialty care providers as the primary participants accountable for quality and cost outcomes.

After consideration of public comments, we are finalizing the inclusion of MIPS Q236: Controlling High Blood Pressure in the heart failure quality measure set as proposed at § 512.725(b)(4).

(v) Functional Status Assessments for Heart Failure (MIPS Q377)

We proposed including Functional Status Assessments for Heart Failure (MIPS Q377) in the heart failure quality measure set in ASM because patients with heart failure often experience poor functional status and health-related quality of life, both of which tend to decline as the disease progresses.

Assessing functional status is crucial for managing the complex health needs of patients who often have multiple comorbidities. Furthermore, standardized assessment of patient-reported health status using a validated questionnaire can be useful for providing incremental information related to patient functional status and prognosis. It is also an independent predictor of hospitalization and mortality.[206] The measure emphasizes the importance of collecting relevant patient-reported health status from heart failure patients, such as functional limitations, symptom burden, and quality of life. It supports the creation of a dynamic conversation between patients and providers regarding care goals and priorities, which we believe can facilitate shared decision-making, empower patients, and incentivize clinicians to incorporate patient voice and lived experience in clinical care activities. This measure is appropriate for ASM as it encourages cardiologists to regularly assess, monitor, and help improve the functional status of their heart failure patients, which are crucial for providing patient-centered care and aligning treatment plans with individual goals and priorities. In addition, this measure aligns with other quality measurement efforts, such as the Advancing Care for Heart Disease MVP in the Quality Payment Program and the Cardiology Core Quality Measures Collaborative (CQMC) set. We sought comment on our inclusion of this measure in the heart failure quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed inclusion of MIPS Q377: Functional Status Assessments for Heart Failure in the ASM heart failure measure set, noting that the measure should be included as a process measure for the CY 2027 ASM performance year, to ensure data collection is feasible and not overly burdensome to patients or clinicians prior to transitioning to a PRO-PM.

Response: We acknowledge the commenters' support of this measure. We agree that it is beneficial to the measure set in its current state and appreciate the commenters' recognition of its value for heart failure care. The measure balances the burden of reporting while incentivizing functional status assessments, which are critical components of comprehensive heart failure management.

Comment: A few commenters expressed concern about the proposed inclusion of MIPS Q377:

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[206] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063.

Functional Status Assessments for Heart Failure measure in the ASM heart failure measure set. A commenter shared their concerns regarding the measure's feasibility and benchmarking, noting that limitations in data capture could unfairly penalize clinicians regardless of care quality. Another commenter expressed concern that some patients may require more than 180 days for meaningful improvement, depending on disease severity and comorbidities, noting that the measure timeframes must account for these actions.

Response: We appreciate the commenter's feedback. We understand the concerns about data capture feasibility and potential penalties for clinicians regardless of care quality. Success in ASM may mean ensuring that patient healthcare data is entered and captured in EHRs appropriately, and we are providing significant advance notice as the model does not start until 2027, thereby giving participants ample time to implement practices and systems to address concerns about data capture capabilities.

Regarding concerns about meaningful improvement within 180 days, we want to clarify that the measure in its current form only looks for documentation that a valid and standardized functional status assessment tool is being administered within 180 days before or after a qualifying heart failure encounter. This measure does not look for clinical improvement during that timeframe, rather, it focuses on whether appropriate assessment tools are being used to evaluate patient functional status as part of comprehensive heart failure care. The measure is designed to promote the systematic use of validated assessment instruments that can inform treatment decisions and care planning, rather than requiring specific improvement outcomes within the specified timeframe.

We note that the Functional Status Assessments for Heart Failure (MIPS Q377) measure is currently a process measure. We proposed that the process measure would be included for the 2027 ASM performance year, while we explore the benefit and applicability of developing a patient-reported outcome-based performance measure (PRO-PM). The current measure ensures a functional status assessment is completed. A PRO-PM would hold the ASM participant accountable for not only collecting patient-reported data but also improving or slowing progression of decline in functional status over time. We believe this would capture more meaningful changes in patient care. We sought comments on our proposal to include the Functional Status Assessments for Heart Failure (MIPS Q377) measure in ASM, the applicability of the measure as a PRO-PM, and whether the PRO-PM, if available, should be included

in the heart failure quality measure set for future performance years of ASM.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support development of the proposed MIPS Q377: Functional Status Assessments for Heart Failure measure into a PRO-PM and expressed concern that the measure incorporates factors that are beyond clinician control, such as patient-specific social risk factors and patient literacy levels. Another commenter noted that the inclusion of PRO-PMs adds new burdens with limited demonstrated value. The commenter also stated that implementation requires new workflows, vendor contracts, and high costs. The commenter recommended that if PRO-PMs are to be included, CMS should allow clinicians flexibility in vendor selection, ensure that acceptable instruments are freely available, and provide technical assistance and phased adoption.

Response: We appreciate the feedback regarding the proposed MIPS Q377: Functional Status Assessments for Heart Failure measure and concerns about its potential development into a PRO-PM. We are finalizing the inclusion of the process version of this measure in this rule, not the PRO-PM version. We are continuing to explore whether a PRO-PM version is appropriate for future implementation and will take these concerns into account during this evaluation process.

We are committed to ensuring that measures included in the ASM measure set prioritize clinical acceptability while minimizing administrative burden on ASM participants. Under the potential development of a PRO-PM, we would seek to allow flexibility where possible in survey instruments used, recognizing the diverse needs and capabilities of different practice settings. We understand the concerns about factors beyond clinician control, such as patient-specific social risk factors and literacy levels and will carefully consider these limitations in any future PRO-PM development.

Any future implementation of this measure as a PRO-PM would be clearly indicated through future notice-and-comment rulemaking, which would provide ample time for adoption by ASM participants. We would also consider opportunities to support participants and phased implementation. We recognize the workflow changes, vendor considerations, and associated costs that PRO-PM implementation may require, and we are committed to working with interested parties to address these challenges should we move forward with PRO-PM development in the future.

Comment: A few commenters supported CMS' development of a validated PRO-PM for the proposed MIPS Q377: Functional Status Assessments for Heart Failure measure. A commenter noted that the PRO-PM would demonstrate a meaningful shift from documentation-based processes to measures of patient experience and lived health outcomes while another commenter stated that the PRO-PM would allow CMS to hold ASM participants accountable not only for completing assessments but also for improving or maintaining patients' functional status over time. However, a few commenters noted possible challenges around licensing, data sources, and inequitable scoring if a PRO-PM is implemented. A commenter recommended that the future PRO-PM for Functional Status Assessments for Heart Failure should not require licensing costly proprietary content. A commenter recommended that CMS phase in this measure as a reporting-only measure or include it as an ASM improvement activity.

Response: We appreciate the supportive feedback regarding the potential development of a PRO-PM for the proposed MIPS Q377: Functional Status Assessments for Heart Failure measure. We are finalizing the inclusion of the process version of this measure in this rule, not a PRO-PM version. We are continuing to explore if a PRO-PM would be appropriate and will take this support into account during this evaluation process. We agree that this tool would improve adherence to completing assessments and improving functional status over time, representing a meaningful shift from documentation-based processes to measures of patient experience and lived health outcomes. We understand the comments around licensing and data sources, and would consider these issues if the measure is developed into a PRO-PM. We recognize the importance of avoiding costly proprietary content requirements and ensuring equitable scoring across diverse patient populations. If a PRO-PM is developed and included in ASM, we would indicate it in advance via notice-and-comment rulemaking and would ensure there is adequate time for the survey(s) to be implemented.

We also received broad feedback on the heart failure quality measure set. The following is a summary of these comments and our responses.

Comment: Many commenters generally supported the proposed ASM heart failure quality measure set. A few commenters supported the use of PRO-PMs in the ASM heart failure quality measure set. A commenter shared their belief that the proposed PRO-PMs in ASM elevate patient voice and incentivize clinicians to be more responsive to the patient's treatment outcomes. Another commenter

noted that the proposed quality measures in the ASM heart failure measure set would support early intervention of acute symptoms, self-management, and improve overall quality of care for patients with heart failure. A commenter recommended that CMS consider including outpatient management of worsening signs and symptoms in patients with heart failure and incorporating guidance from the 2022 AHA/ACC/HFSA Heart Failure Guideline. Another commenter appreciated CMS for the proposed measure set's conciseness and alignment with the Core Quality Measures Collaborative's work.

Response: We appreciate the supportive comments regarding the proposed ASM heart failure quality measure set and the recognition of its alignment with established quality frameworks. We will continue to explore opportunities for PRO-PM in the measure set. Our goal is to support early intervention and management of heart failure symptoms while ensuring that the measure set is appropriate for all levels of heart failure care. We appreciate the feedback regarding incorporating guidance from the 2022 AHA/ACC/HFSA Heart Failure Guideline and will consider how to better address outpatient management of worsening signs and symptoms in future iterations. The conciseness of the measure set and its alignment with the Core Quality Measures Collaborative's work reflects our commitment to reducing provider burden while maintaining meaningful quality assessment. We believe this balanced approach will support improved self-management capabilities and overall quality of care for patients with heart failure across the care continuum.

Comment: A commenter shared their concern that none of the proposed measures in the ASM heart failure measure set are PRO-PMs, noting that two of the heart failure quality measures, Beta Blocker Therapy for LVSD and ACE/ARB/ARNI for LVSD, only apply to patients with reduced ejection fraction while the cost measures include patients with preserved ejection fraction.

Response: We appreciate the commenter for the feedback regarding PRO-PMs and the scope of quality measures in the ASM heart failure measure set. We are limited by which measures are currently available and validated for heart failure care, and we believe the selected measures are appropriate for assessing quality care delivery in this population. We are continuing to explore opportunities for developing a heart failure-specific PRO-PM, but we believe the process-based quality measures in our current set appropriately assess evidence-based care delivery. Regarding the concern about reduced ejection fraction measures, while the cost measures include patients with preserved ejection fraction, our

goal is to improve care for all heart failure patients, not just certain subsets, though we recognize the clinical nuances and heterogeneity in their care needs. Certain quality measures are only applicable to specific patient subsets and should be applied as they were developed and specified, rather than being extended to other populations for which they were not designed or validated. We acknowledge that we currently do not have quality measures specifically for heart failure with preserved ejection fraction (HFpEF), partly because clinical guidelines for HFpEF continue to evolve and measure development has not kept pace with these advances. We will be assessing the quality measure set throughout the course of the model and could propose changes or additions in future years through notice-and-comment rulemaking as new evidence-based measures become available and validated for the heart failure population.

Comment: Several commenters offered recommendations on the proposed ASM heart failure quality measure set. A commenter recommended that CMS incorporate incentives for early screening and diagnosis of cardio-renal-metabolic (CRM) conditions to slow progression of CRM conditions and improve health outcomes. Another commenter recommended CMS adding palliative care as a treatment option for heart failure patients, noting alignment with the American Heart Association's recommendation to integrate palliative care for patients with advanced cardiovascular disease. Another commenter recommended incorporating patient experience measures, such as the CAHPS survey, to assess the domains of patient communication, care coordination, and shared decision-making. Another commenter recommended that CMS includes Preventive Care and Screening: Screening for Depression and Follow-up Plan measure in the heart failure quality measure set, because many heart failure patients suffer from depressive symptoms. A few commenters recommended that ASM recognize and accommodate novel therapeutic innovations and incorporate newer therapies, such as statins and SGLT2 inhibitors. A commenter recommended that CMS consider including future measures for novel therapies, cardiology visits, and medical nutrition therapy.

Response: We appreciate the feedback on additional measures and elements to improve the quality of care for heart failure patients, such as those focused on early screening and diagnosis of CRM conditions, palliative care, CAHPS patient experience measures, depression screening, novel medical therapies, and composite guideline-directed medical therapy (GDMT). With the heart failure quality

measure set, we strive to balance clinical applicability and minimal burden on participants and patients. Due to this balance, the development of new measures is often unfeasible, considering the significant effort involved by CMS and participants in standing them up operationally.

We will take these suggestions into consideration. While we do not plan to adjust the quality measure sets during the model test period, we would consider modifications for significant changes in clinical guidelines, availability of new measures, or where the addition or removal of measures would incentivize quality care. Comment: A commenter shared their concern about using PRO-PMs as the foundation of ASM, noting the difficulty to collect data in vascular surgery populations.

Response: We appreciate the commenters for their feedback. We believe that PROMs are valuable tools in quality measurement as they capture the patient's perspective on their health status and treatment outcomes, which is essential for comprehensive quality assessment. However, we recognize that PRO-PMs do not exist in every clinical field yet, and their development and validation require significant time and resources.

We would like to clarify that ASM focuses specifically on heart failure and low back pain conditions, not vascular surgery. The measure sets are tailored to these specific clinical areas where an appropriate PROM has been identified and validated. We understand that different surgical specialties, including vascular surgery, may face unique challenges in implementing PROMs due to factors such as patient acuity, procedural complexity, and varying recovery timelines that can make standardized outcome measurement more difficult. However, because ASM does not focus on vascular surgery specialists, we believe that this comment is out of ASM's scope.

Comment: A few commenters recommended that CMS use existing MVPs that may be applicable to heart failure, such as the Advancing Care for Heart Disease MVP, since using existing MVPs would minimize reporting burden

Response: We appreciate the commenter's recommendation to use existing MVPs that may be applicable to heart failure, such as the Advancing Care for Heart Disease MVP. We agree that overlap in measures between programs can reduce administrative burden on providers and improve alignment across CMS quality initiatives. For this reason, during our measure selection process, we aligned as much as possible with the Advancing Care for Heart Disease MVP. Four of our five heart failure measures are the

same as those included in the MVP, demonstrating our commitment to reducing duplicative reporting requirements while maintaining clinically meaningful quality assessment. This alignment supports provider efficiency by allowing participants to leverage existing workflows and data collection processes they may already have in place for MVP reporting. Also, acknowledging the burden this may present to small practices, we are finalizing allowing for flexibility for small practices to report quality measures in the quality ASM performance category at the TIN-level, as further described in section III.C.2.d.(1).(b) in this final.

Comment: A commenter recommended that CMS consider including arrhythmia detection in the ASM heart failure measure set, noting that the measure would help address a key, often undetected driver of heart failure morbidity and cost, and align with HHS's Make America Healthy Again initiative. The commenters recommended adding quality measures in the ASM heart failure measure set, such as documented rhythm monitoring, appropriate management initiation, and reduction in unplanned cardiovascular admissions attributable to atrial fibrillation.

Response: We appreciate the feedback regarding the recommendation to include arrhythmia detection measures in the ASM heart failure quality measure set. We recognize that arrhythmias, particularly atrial fibrillation, can be an important and often undetected driver of heart failure morbidity and healthcare costs. However, we do not currently have a validated MIPS measure that addresses this specific clinical nuance, particularly in regard to heart failure admissions and the comprehensive arrhythmia management components.

We considered existing measures such as those focused on atrial fibrillation and atrial flutter anticoagulation management, recognizing that some patients with heart failure also have atrial fibrillation. Ultimately, we did not choose to include these measures because they only apply to a subset of the heart failure population, and we aimed to develop a measure set that would be broadly applicable to the diverse heart failure patient population served by ASM participants.

We appreciate the commenter noting the alignment with broader health initiatives and the clinical importance of rhythm monitoring and appropriate management. While we do not plan to adjust the quality measure sets during the model test period, we would consider modifications for significant changes in clinical guidelines, availability of new measures, or where the addition or removal of measures would

incentivize quality care. We will consider incorporating arrhythmia-related measures in future iterations of the ASM heart failure quality measure set should validated measures become available. The feedback regarding documented rhythm monitoring, appropriate management initiation, and reduction in unplanned cardiovascular admissions attributable to atrial fibrillation will inform our ongoing evaluation of potential measure enhancements.

Comment: A few commenters expressed concerns about the proposed ASM heart failure quality measure set, noting that it may disadvantage 50 percent of heart failure patients with HFpEF as well as patients with advanced heart failure. The commenters shared their belief that the proposed quality measures are primarily aligned with evidence-based treatments for HFrEF and recommended that CMS develop dedicated quality measures for HFpEF populations that reflect the limited evidence base and different therapeutic approaches for these patients. The commenters encouraged CMS to adopt additional measures to incentivize quality of care for all heart failure patients.

Response: We appreciate the feedback regarding concerns about the proposed ASM heart failure quality measure set and its potential impact on patients with heart failure with preserved ejection fraction (HFpEF) and advanced heart failure. Our goal is to improve care for all heart failure patients, not just certain subsets, though we recognize the clinical nuances and heterogeneity in their care management approaches. We acknowledge the difference between patients with HFpEF and those with HFrEF, and that clinical guidelines for HFpEF are still evolving. We note that certain quality measures are only applicable to specific patient subsets based on the clinical evidence and populations for which they were developed and validated, and we would want to apply these measures as they were originally specified rather than extending them inappropriately to other populations. We also note that there are limited existing quality measures that apply to HFpEF. We will be assessing the quality measure set throughout the course of the model and could propose changes in future years as the clinical evidence base evolves and new validated measures become available. While we strive to incentivize quality care for all heart failure patients, we must balance this goal with the practical limitations of available, validated quality measures. We appreciate the clinical expertise reflected in these comments and will continue to engage with the heart failure clinical community to ensure our quality measurement approach supports optimal care for all patients across the heart failure spectrum.

Comment: A commenter shared their concern that patients with advanced heart failure may encounter treatment paradoxes, where standard care protocols may not be appropriate, potentially compromising the validity of quality measurement and unfairly penalizing clinicians caring for the most complex patients. The commenter, therefore, recommended that patients classified as New York Heart Association (NYHA) stage D be systematically excluded by CMS from all proposed quality measures.

Response: We appreciate the commenters for expressing their concerns about patients with advanced heart failure and the potential impact on quality measurement validity. We agree that there are scenarios in which advanced heart failure patients may present clinical complexities that could be less appropriate for assessing a participant's performance. For this reason, each quality measure includes elements such as denominator exclusions and risk adjustment methodologies specifically designed to address these challenging clinical situations. We also believe that our overall performance assessment approach, which includes multiple elements beyond quality measures and compares similar providers treating comparable patient populations, will help mitigate potential issues related to caring for complex patients. While we understand the clinical rationale for the recommendation, we believe that systematically excluding Stage D patients would be against ASM's overall goal of improving care for all heart failure patients and holding providers accountable for the full spectrum of patients they treat.

Comment: A commenter recommended that CMS clarify whether the proposed medication-based measures in the ASM heart failure measure set would apply to all heart failure patients under a clinician's care or only to those patients attributed to the clinician within ASM. The commenter expressed concerns that applying these measures to all heart failure patients could increase reporting burden, while limiting them to attributed patients may result in issues with sample size and representativeness.

Response: We appreciate the comment requesting clarification on the scope of the proposed measures in the ASM heart failure quality measure set. The medication measures (ACE Inhibitor or ARB or ARNI Therapy for LVSD and Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction) are all-payer measures, meaning they are reported regardless of insurance type for those patients that they apply to. We believe this approach is important because it allows full representation of an ASM participant's care across their entire patient panel, provides more stable denominators for meaningful measurement, enables streamlined workflows for reporting, and delivers improved quality insights. While we

understand the concerns about potential reporting burden when applying measures to all heart failure patients under a clinician's care, we believe that the benefits of comprehensive measurement outweigh these concerns. The all-payer approach ensures that quality assessment reflects the totality of care provided by ASM participants rather than being limited to a subset that may not be representative of their overall practice patterns. Additionally, this approach addresses the sample size and representativeness issues that could arise from limiting measurements to only attributed patients, which could result in unreliable or skewed performance data.

Comment: A commenter recommended that CMS clarify whether heart failure patients without a confirming echocardiogram would be excluded from the proposed ASM heart failure quality measure set, noting that attributing such patients to specialists without definitive diagnostic confirmation would be inappropriate.

Response: To clarify for the commenter, each measure includes specific inclusion criteria that determine which portion of the participant's patient panel is included in the denominator or numerator for that particular measure. The measures do not universally require verification that the patient has heart failure with a confirming echocardiogram as part of their standard specifications. We believe the all-payer and patient panel approach of the measures is appropriate as it allows the measures to comprehensively assess provider quality across their entire relevant patient population. Each measure has been rigorously tested for reliability and validity in the specific population it targets, and modifying these specifications to look exclusively for heart failure patients with a confirming echocardiogram would jeopardize the measures' established validity and reliability. The inclusion criteria for each measure are designed to identify the appropriate patient population based on the clinical evidence and methodology that supports that specific measure. This approach ensures that quality assessment reflects real-world clinical practice patterns while maintaining the scientific integrity of the measurement tools. After reviewing public comments, we are finalizing the inclusion of Functional Status Assessments for Heart Failure (MIPS Q377) as proposed at § 512.725(b)(5). We intend to consider re-specification of this measure into a PRO-PM through future notice-and-comment rulemaking.

(c) Quality Measure Set for the ASM Low Back Pain Cohort

We proposed at § 512.725(c)(1) through (5) to include the following measures in the low back pain quality measure set. Each ASM low back pain participant must report each finalized measure using one of the collection types specified in Table B-D4.

(i) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain, Respecified to Be Relevant to ASM Participants Treating Low Back Pain

We proposed to include a respecified MRI Lumbar Spine for Low Back Pain measure in the low back pain quality measure set. We believe this administrative claims-based measure can effectively assess overuse and incentivize reductions in inappropriate MRI imaging for low back pain. Routine imaging (such as MRI) is not recommended for patients with non-specific low back pain in the absence of certain clinical indicators with concerning features.[207] However, studies have shown that a significant proportion of patients with low back pain undergo imaging, often within the first few weeks of symptom onset, despite the lack of clear indication.[208] Overuse of imaging for low back pain can lead to unnecessary health care costs and potential patient harm from incidental findings that may prompt further unnecessary testing or procedures.[209,210] By including this measure in the low back pain quality measure set, ASM aims to incentivize adherence to evidence-based guidelines and a reduction of unnecessary MRIs for patients with uncomplicated low back pain, particularly in the initial stages of evaluation and management. We believe this could also have a positive impact on patient experience as it reduces time spent at medical appointments and health care costs. Furthermore, as an administrative claims measure, ASM participants would not have to report data for this measure, reducing reporting burden.

MRI Lumbar Spine for Low Back Pain measure was specified for use in Hospital Outpatient Departments at the facility level and was previously included in the Hospital Outpatient Quality Reporting Program (HOQRP) as OP-8 (73 FR 68766).[211] Part of our re-specification efforts would

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[207] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020. https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf.
[208] Medicare Payment Advisory Commission. Health Care Spending and the Medicare Program: A Data Book. Medicare Payment Advisory Commission; July 2021. Accessed [insert access date]. https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec7_SEC.pdf.
[209] Litkowski PE, Smetana GW, Zeidel ML, Blanchard MS. Curbing the Urge to Image. *The American Journal of Medicine*. 2016;129(10):1131-1135. doi:*https://doi.org/10.1016/j.amjmed.2016.06.020*.
[210] Chou R. Diagnostic Imaging for Low Back Pain: Advice for High-Value Health Care From the American College of Physicians. *Annals of Internal Medicine*. 2011;154(3):181. doi:*https://doi.org/10.7326/0003-4819-154-3-201102010-00008*.
[211] Hospital Outpatient Quality Reporting | Partnership for Quality Measurement. P4qm.org. Published 2025. Accessed April 23, 2025. https://p4qm.org/taxonomy/term/216.

involve ensuring validity and reliability at the TIN/NPI level. We are also exploring the denominator criteria of the measure and potentially redefining the denominator. This potential change is pending further internal analyses to determine whether participants would be able to meet denominator minimum and specification changes and ensure the measure accurately identifies unwarranted MRI usage. We would propose the measure's specifications through notice-and-comment rulemaking when available and in advance of using the measure in the low back pain cohort.

We solicited comments on the re-specification and inclusion of MRI Lumbar Spine for Low Back Pain measure in the low back pain quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the proposed MRI Lumbar Spine for Low Back Pain measure in the ASM low back pain measure set. A few commenters did not support the inclusion of the measure, noting the measure is still in development resulting in limited insight into the measure specifications. A few commenters recommended that CMS defer the inclusion until the measure is fully developed, clinically vetted, and made available for public review. A few commenters noted that the measure was previously removed from the Hospital Outpatient Quality Reporting program due to stable performance and low average volumes, as well lack of alignment with current clinical guidelines. A commenter recommended CMS to clarify the timeline for measure development and validation. Another commenter expressed concern that the measure could inappropriately drive clinicians to focus narrowly on reducing utilization, rather than ensuring appropriate and timely imaging when clinically indicated. The commenter recommended that CMS replace the proposed MRI Lumbar Spine for Low Back Pain measure with the Falls: Plan of Care measure. A few commenters recommended CMS to clarify attribution and reporting requirements for the measure. A commenter recommended that CMS provide specifications for MRI utilization and identify high-risk medications. Another commenter expressed concern that the measure would not accurately reflect the quality of care or be applicable to all ASM low back pain cohort participants.

Response: We appreciate the commenters for their feedback regarding the proposed MRI Lumbar Spine for Low Back Pain measure in the ASM low back pain quality measure set. Based on this feedback,

we are not finalizing the MRI Lumbar Spine for Low Back Pain measure in the ASM low back pain quality measure set at this time. We are continuing to explore this measure and/or other measures focused on low back pain low-value care that are claims-based for inclusion by the January 1, 2027 ASM start date. We will propose the measure we would like to move forward with through future notice-and-comment rulemaking. We believe that, given our intention to use an administrative claims-based measure, which limits participant burden, indicating the measure and specifications during the CY 2027 PFS notice of public rulemaking would provide ample time for participants to prepare for implementation. We acknowledge the concerns raised about measure development status, clinical validation, and the need for public review, as well as the feedback regarding the measure's previous removal from other quality reporting programs. Our commitment is to ensure that any low-value care measure we ultimately include will be fully developed, clinically appropriate, and aligned with current evidence-based guidelines. We will continue to work with clinical experts and interested parties to identify the most appropriate and effective measure while ensuring that clinically indicated care is not compromised.

Comment: A commenter recommended that CMS re-specify the proposed MRI Lumbar Spine for Low Back Pain measure in the ASM low back pain quality measure set, noting that the measure should evaluate care based on specific lumbar spine diseases or conditions, including lumbosacral and sacroiliac conditions, rather than grouping all chronic low back pain patients together. The commenter also recommended that CMS provide a list of ICD-10 codes that would trigger a “non-specific low back pain” classification, as well as the CPT codes included within the non-specific low back pain group.

Response: We appreciate the commenter’s feedback on the proposed MRI Lumbar Spine for Low Back Pain measure in the ASM low back pain quality measure set. We are not finalizing the inclusion of the MRI Lumbar Spine for Low Back Pain measure in the ASM measure set at this time. We intend to revisit this measure or possible alternatives in the CY 2027 PFS notice of public rulemaking. At that time, we may consider the recommendation to re-specify the measure to evaluate care based on specific lumbar spine diseases or conditions, including specific diagnostic categorizations and appropriate code specifications that better reflect the clinical nuances of different lumbar spine conditions.

After consideration of public comments, we are not finalizing inclusion of Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain, Respecified to Be Relevant to ASM Participants

Treating Low Back Pain in the low back pain quality measure set at this time. We intend to revisit this measure or alternatives in future notice-and-comment rulemaking.

(ii) Use of High-Risk Medications in Older Adults (MIPS Q238)

We proposed to include the Use of High-Risk Medications in Older Adults (MIPS Q238) measure in the low back pain quality measure set. Older adults with low back pain who receive a prescription for a high-risk medication as part of their treatment plan, may have a range of adverse events, including medication side effects, drug interactions, a prescribing cascade, or hospitalization. Individuals ages 65 and older are more likely to have multiple chronic conditions, increasing their risk for adverse drug effects associated with polypharmacy.[212] Forty percent of individuals 65 and older filled at least one prescription for a potentially inappropriate medication and 13 percent filled two or more, leading to as much as $7.2 billion spent per year on inappropriate medications in older adults.[213,214] Several of the medications included in the measure are prescribed for treatment of musculoskeletal conditions and pain, such as skeletal muscle relaxants and tricyclic antidepressants.[215,216,217] Skeletal muscle relaxants may be prescribed as an alternative to conventional pain medication; however, they carry considerable risk of falls and associated morbidity due to common side effects of dizziness, drowsiness, and hypotension. One study found that elderly patients who were using skeletal muscle relaxants were 2.25 times more likely to visit the emergency room for a fall or fracture than elderly patients who were not prescribed these medications.[218] Similarly, a meta-analysis exploring the risks associated with use of tricyclic antidepressants in elderly patients found a significant increased risk of falls and fracture.[219] In addition to

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[212] Medicare Payment Advisory Commission. Polypharmacy and opioid use among Medicare Part D enrollees. In: Report to the Congress: Medicare and the Health Care Delivery System. June 2015. Chapter 5. Accessed [insert access date]. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf.

[213] Fick DM, Mion LC, Beers MH, L. Waller J. Health outcomes associated with potentially inappropriate medication use in older adults. *Research in Nursing & Health*. 2008;31(1):42-51. doi:https://doi.org/10.1002/nur.20232.

[214] Fu AZ, Jiang JZ, Reeves JH, Fincham JE, Liu GG, Perri M. Potentially Inappropriate Medication Use and Healthcare Expenditures in the US Community-Dwelling Elderly. *Medical Care*. 2007;45(5):472-476. doi:https://doi.org/10.1097/01.mlr.0000254571.05722.34.

[215] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020. https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCar.

[216] Santandreu J, Francisco Félix Caballero, M Pilar Gómez-Serranillos, González-Burgos E. Association between tricyclic antidepressants and health outcomes among older people: A systematic review and meta-analysis. *Maturitas*. 2024;188:108083-108083. doi:https://doi.org/10.1016/j.maturitas.2024.108083

[217] Castillo S. Inappropriate Use of Skeletal Muscle Relaxants in Geriatric Patients. Uspharmacist.com. Published January 21, 2020. Accessed April 17, 2025. https://www.uspharmacist.com/article/inappropriate-use-of-skeletal-muscle-relaxants-in-geriatric-patients#:~:text=Skeletal%20muscle%20relaxants%20are%20on,opioids%20in%20the%20geriatric%20population.

[218] Castillo S. Inappropriate Use of Skeletal Muscle Relaxants in Geriatric Patients. Uspharmacist.com. Published January 21, 2020. Accessed April 23, 2025. https://www.uspharmacist.com/article/inappropriate-use-of-skeletal-muscle-relaxants-in-geriatric-patients?utm_source=TrendMD&utm_medium=cpc&utm_campaign=US_Pharmacist_TrendMD_0.

[219] Santandreu J, Francisco Félix Caballero, M Pilar Gómez-Serranillos, González-Burgos E. Association between tricyclic antidepressants and health outcomes among older people: A systematic review and meta-analysis. *Maturitas*. 2024;188:108083-108083. doi:https://doi.org/10.1016/j.maturitas.2024.108083.

the morbidity and substantial costs associated with falls in the older adult population, falls in a patient with low back pain could significantly worsen their condition and functional status. We believe including this measure in the low back pain quality measure set could encourage ASM participants to be more cautious in their prescribing of high-risk medications to patients with low back pain and potentially prevent falls and other adverse events that may negatively impact patient outcomes. It also could align clinical practice with efforts to avoid inappropriate describing in older adults, such as the Beers criteria, and deprescribe where appropriate.[220] We believe the measure may promote positive changes in care delivery, such as incorporating regular medication review and reconciliation. This measure could be particularly impactful in ASM given the promotion of specialty and primary care integration as a goal of the model. We solicited comments on our inclusion of the Use of High-Risk Medications in Older Adults (MIPS Q238) measure in the ASM low back pain quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support the proposed inclusion of MIPS Q238: Use of High-Risk Medications in Older Adults in the ASM low back pain quality measure set. A few commenters expressed concern that the measure may unfairly penalize clinicians for appropriate prescribing of medications and recommended that CMS monitor the impact of this measure. The commenters shared their belief that clinicians should be encouraged to individualize medication regimens relevant to the patient's unique needs, rather than being penalized for prescribing a "high risk" medication. A commenter recommended that CMS should not hold ASM participants accountable for use of high-risk medications to manage care for low back pain, noting that these medications are indicative of patients with a wide range of diagnoses beyond low back pain, are often prescribed or initiated by a primary care physician rather than specialists, limiting the specialist's authority to discontinue or alter those prescriptions. Another commenter recommended that CMS should test the reliability and validity of the measure at the individual level prior to its inclusion in ASM, noting that the measure was developed at the health-plan level and not the individual clinician level. Another commenter expressed concern that the

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[220] American Geriatrics Society. American Geriatrics Society 2023 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. *Journal of the American Geriatrics Society*. 2023;71(7). doi:https://doi.org/10.1111/jgs.18372.

measure is topped out.

Response: We appreciate the feedback regarding the proposed inclusion of MIPS Q238: Use of High-Risk Medications in Older Adults in the ASM low back pain quality measure set. We want to note that the use of two or more high-risk medications is a concern for overall health, and there are not common circumstances in which patients would have this medication mix and it would be appropriate. This measure has been extensively reviewed and approved for use because of its ability to discern inappropriate prescribing patterns. Furthermore, if there were a rare instance of a medication combination that would be captured in the numerator of this measure being relevant to a patient, the rest of the ASM participant's patient panel would balance out this outlier, as the measure focuses on the total percentage of patients 65 years of age and older. The measure largely looks for trends in inappropriate medication use, and providers that would perform the worst are those who have a significant number of patients on these high-risk medications.

Regarding concerns that these medications are applicable to several conditions beyond low back pain, ASM is focused on promoting accountability of our participants for their patients' whole-person health. When seeing a patient, the participant should examine the patient's suite of medications they are on and scrutinize if any are high-risk, especially given the connection between some of these high-risk medications, low back pain, and adverse events like falls. Additionally, if a medication is ordered by a provider who is not the ASM participant, they would not be penalized based on the measure methodology.

Regarding reliability at the TIN/NPI level, we note this measure is currently used in MIPS at the individual clinician level and our model aims to align with MIPS measures and measurement approaches whenever possible. While it can also be used to assess health plan performance, we note that the health plan level is not the only level of reporting or analysis for the measure. We also believe ASM's minimum case count criteria for quality measures as described in section III.C.2.d.(2).(h).(ii) of this final rule will ensure that only participants that meet the case minimum will be scored on the measure. Finally, concerning the topped-out status, we believe the mandatory set of measures in ASM reduces choice compared to MIPS, where providers could typically report measures on which they perform best. We believe mandatory reporting could significantly change the distribution of measure scores and whether the

measure would be considered topped-out in ASM. We refer readers to section III.C.2.d.(2).(i).(iii) of this final rule for further discussion on topped-out measure status in ASM.

Comment: A commenter shared their belief that pharmacists are essential in ensuring patients receive medications that best align with their treatment plan under the proposed MIPS Q238: Use of High-Risk Medications in Older Adults measure in the ASM low back pain quality measure set and recommended that CMS include pharmacists in the ASM, as many of the proposed measures are applicable to them.

Response: We appreciate this comment regarding the important role of pharmacists in medication management and patient care. While ASM does not include pharmacists as ASM participants, we recognize that to succeed, participants would ideally connect with pharmacists and collaborate on optimizing patient care. We believe the overall incentive approach of the model ensures discussion and coordination with the overall care team, which may include a pharmacist. The quality measures, including MIPS Q238: Use of High-Risk Medications in Older Adults, are designed to encourage ASM participants to take a comprehensive approach to patient care that naturally involves collaboration with other healthcare professionals who can contribute to better outcomes. This collaborative approach aligns with our broader goals of promoting coordinated, patient-centered care that leverages the expertise of all relevant healthcare professionals.

After consideration of public comments, we are finalizing the inclusion of the (MIPS Q238) Use of High-Risk Medications in Older Adults in the low back pain quality measure set as proposed at § 512.725(c)(1).

(iii) Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134)

We proposed to including Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Q134) in the low back pain quality measure set because patients with chronic pain conditions, such as low back pain, are at an increased risk of developing depression.[221] Comorbid depression can negatively impact quality of life, treatment adherence, and overall health outcomes.[222] Screening for

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[221] Mullins PM, Yong RJ, Bhattacharyya N. Associations between chronic pain, anxiety, and depression among adults in the United States. *Pain Practice*. 2023;23(6). doi:https://doi.org/10.1111/papr.13220.
[222] Mullins PM, Yong RJ, Bhattacharyya N. Associations between chronic pain, anxiety, and depression among adults in the United States. *Pain Practice*. 2023;23(6). doi:https://doi.org/10.1111/papr.13220.

depression and providing appropriate follow-up care is an essential aspect of comprehensive care for patients with low back pain, as depression may exacerbate pain and worsen functional status.[223] Co-occurring depression has also been found to worsen low back pain outcomes and increase health care costs.[224] Effective management of low back pain often requires a multidisciplinary approach to address the physical, psychological, and emotional aspects of the condition. Including this measure in the ASM low back pain quality measure set would encourage ASM participants treating low back pain to prioritize mental health screening and follow-up care. We believe this would lead to better management of physical and mental health, prevent worsening of a patient's health status, and improve overall outcomes.[225,226] We sought comment on the proposal to include the Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134) measure in the ASM low back pain quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed inclusion of MIPS Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure in the ASM low back pain quality measure set, noting that depression can exacerbate pain and negatively affect function, treatment adherence, and overall health outcomes. A commenter shared their belief that this measure would encourage providers to prioritize mental health screening and follow-up care. Another commenter recommended CMS to clarify whether the proposed measure aligns with the Universal Foundation.

Response: We appreciate the support for the proposed inclusion of MIPS Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure in the ASM low back pain quality measure set. We believe it is vital to whole-person low back pain care, as depression can exacerbate pain and negatively affect function, treatment adherence, and overall health outcomes. This measure encourages providers to prioritize mental health screening and follow-up care, which is essential for comprehensive pain management. This measure does align with the CMS Universal Foundation's and our

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[223] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.
[224] Wong JJ, Tricco AC, Côté P, et al. Association Between Depressive Symptoms or Depression and Health Outcomes for Low Back Pain: a Systematic Review and Meta-analysis. *Journal of General Internal Medicine*. 2021;37(5). doi:https://doi.org/10.1007/s11606-021-07079-8.
[225] Pinheiro MB, Ferreira ML, Refshauge K, et al. Symptoms of Depression and Risk of New Episodes of Low Back Pain: A Systematic Review and Meta-Analysis. *Arthritis Care & Research*. 2015;67(11):1591-1603. doi:https://doi.org/10.1002/acr.22619.
[226] Tagliaferri SD, Miller CT, Owen PJ, et al. Domains of chronic low back pain and assessing treatment effectiveness: A clinical perspective. *Pain Practice*. 2019;20(2). doi:https://doi.org/10.1111/papr.12846.

model aligns with the Center's focus on prevention, wellness, and chronic disease management across CMS programs.

Comment: A few commenters did not support the proposed inclusion of MIPS Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure in the ASM low back pain quality measure set, noting that screening for depression is not specific to patients with low back pain and could also be applied to more diverse patient populations and expressed concern that some clinicians, specifically anesthesiologists and orthopedic surgeons, do not routinely screen for depression. Another commenter shared their belief that using broadly applicable measures for the ASM low back pain cohort illustrates CMS' challenges to create a one-size-fits-all measure set, noting that these measures generally would not lead to meaningful comparisons of clinicians across different specialties and subspecialties.

Response: We acknowledge the comments regarding the proposed inclusion of MIPS Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure in the ASM low back pain quality measure set. While the measure is not exclusive to low back pain, we described in the CY 2026 PFS proposed rule (90 FR 32589 through 32594) how a significant portion of patients who have low back pain also experience depression and that there is an established connection between depression and low back pain. While some specialties may not routinely conduct these screening, we are purposefully incentivizing this activity to occur in ASM to improve whole-person care for low back pain patients. We believe that participants meeting our criteria for inclusion treat enough patients with low back pain that they should be routinely exploring this comorbid condition as part of comprehensive care. The model is limited by the measures available in existence, and we also took several steps to ensure alignment across CMS programs (like MIPS) to reduce administrative burden on providers. However, we believe that each measure is clinically important to the conditions we are focusing on and, therefore, believe they create a cohesive set that can appropriately identify differences in physician performance and promote quality improvement. We believe that encouraging this practice across different specialties will ultimately lead to improved patient outcomes for those suffering from low back pain.

After consideration of public comments, we are finalizing the inclusion of the (MIPS Q134) Preventive Care and Screening: Screening for Depression and Follow-Up Plan in the low back pain quality measure set as proposed at § 512.725(c)(2).

(iv) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128)

We proposed to including the Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128) measure in the low back pain quality measure set because obesity can predispose patients to and exacerbate chronic low back pain.[227,228] Incorporating BMI screening and related follow-up into the care of patients with low back pain can improve outcomes by reducing the severity and recurrence of low back pain. The inclusion of this measure in the ASM low back pain quality measure set would incentivize a more holistic approach to low back pain management, addressing both the physical and lifestyle factors contributing to the condition. We believe ASM participants treating low back pain can play a crucial role in preventing and addressing modifiable risk factors like obesity and providing appropriate follow-up plans for weight management. In addition, this measure aligns with those used in other quality programs, such as the Rehabilitative Support for Musculoskeletal Care MVP in the Quality Payment Program. We sought comments on the proposal to include Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128) in the ASM low back pain quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed inclusion of MIPS Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan in the ASM low back pain quality measure set, noting that including the measure with weight management strategies could help reduce low back pain as obesity is a modifiable risk factor which may exacerbate chronic low back pain.

Response: We appreciate and agree that this measure can be beneficial for patients with low back pain. The inclusion of MIPS Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan in the ASM low back pain quality measure set recognizes the important connection between obesity and chronic low back pain. We agree that obesity is a modifiable risk factor that may

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[227] Zhang TT, Liu Z, Liu YL, Zhao JJ, Liu DW, Tian QB. Obesity as a Risk Factor for Low Back Pain: A Meta-Analysis. *Clinical Spine Surgery*. 2018;31(1):22-27. doi:https://doi.org/10.1097/BSD.0000000000000468.

[228] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.

exacerbate chronic low back pain, and incorporating weight management strategies through BMI screening and follow-up planning can help reduce pain and improve patient outcomes.

Comment: A few commenters did not support the proposed inclusion of MIPS Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan in the ASM low back pain quality measure set. A commenter shared their concerns that using BMI as the sole indicator for screening and follow-up is not aligned with current clinical understanding. Another commenter recommended that the measure be revised to incorporate more meaningful and individualized indicators of health risk, noting concerns that BMI is an outdated and overly simplistic tool. Another commenter expressed concern that BMI screening is not routinely reported by some specialists, specifically anesthesiologists. A commenter expressed concern that the current measure specifications apply for larger patient populations, rather than just patients with low back pain. Another commenter expressed concern that the measure does not appropriately address the desired outcome of holding patients accountable for meeting their weight loss goals and recommended CMS to incentivize weight-loss programs and reimbursement for counseling or nutrition services for motivating patients to lose weight.

Response: We appreciate the comments regarding the proposed inclusion of MIPS Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan in the ASM low back pain quality measure set. As we described in the CY 2026 PFS proposed rule (90 FR 32589 through 32594), while the measure is not specific to low back pain patients, a significant portion of patients have low back pain and there is a well-documented connection between elevated BMI and low back pain, including increased pain severity, functional disability, and treatment complexity. Clinical evidence demonstrates that excess weight places additional mechanical stress on the spine and can contribute to inflammatory processes that exacerbate pain conditions. While some specialties do not routinely conduct these screenings, we are purposefully incentivizing this activity in ASM to improve whole-person care for low back pain patients. We believe participants meeting our criteria for inclusion treat enough patients with low back pain that they should be routinely exploring this comorbid condition as part of comprehensive care management. This approach recognizes that effective low back pain treatment often requires addressing underlying contributing factors rather than focusing solely on symptom management. We also do not see harm in this measure reaching beyond the low back pain population as BMI screening

activity is widely applicable and may positively impact other conditions commonly managed by these providers, including cardiovascular disease, diabetes, and other musculoskeletal conditions. The model is limited by the measures available in existence, and we also took several steps to ensure alignment across CMS programs, like MIPS, to reduce administrative burden on providers while maintaining clinical relevance.

Regarding concerns about BMI as a screening tool, we acknowledge the ongoing clinical discussions about BMI limitations and the evolution toward more individualized health risk indicators. However, BMI remains a widely accepted, standardized, and practical measure across healthcare settings that provides valuable population-level health information. The measure focuses on screening and follow-up planning rather than BMI as the sole determinant of health risk, allowing providers flexibility in developing individualized treatment approaches based on comprehensive patient assessment. The model does allow participants to provide beneficiary incentives that could be used to improve care outcomes, including those related to BMI management, weight loss programs, and comprehensive lifestyle interventions. We refer readers to section III.C.2.k.(1) of this final rule for further information on beneficiary incentives. These incentives can support patient accountability and engagement in weight management goals while providing resources for counseling and nutrition services as recommended by commenters. Additionally, other CMS programs and Innovation Center models, aligning with the prevention focus of CMS, encourage these screening activities and offer possibilities for improvement in patient outcomes through early identification and coordinated intervention strategies.

Comment: A commenter requested clarification on how ASM participants that are part of a group would "count" a patient when reporting this measure. For example, they noted that if each clinician must report their own measures, the EHR may require each clinician to document a BMI screening for the same patient, even if it was already done by another clinician the day before. This could lead to the patient having to undergo the same screening and counseling twice, which is redundant. Alternatively, if a practice reports quality measures as a group, once a BMI screening is documented for a patient, regardless of which clinician did it, the EHR will recognize the measure has been met and other clinicians in the group will not be prompted to repeat the BMI screening for the same patient within the same reporting period.

Response: We appreciate the commenter's request for clarification on how ASM participants within group practices would report the MIPS Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan measure. This is an important operational question that affects both provider workflow and patient experience. The BMI may be documented in the medical record of the provider or in outside medical records obtained by the provider. Per the measure specifications, the measure only requires a BMI documented during the current encounter or during the measurement period AND who had a follow-up plan documented if BMI was outside of normal parameters.[229] Therefore, the screening should not need to be repeated. If the BMI is documented in the patient's chart, the BMI screening will not need to be repeated for the provider to get credit for this measure, addressing concerns of duplication of efforts.

After consideration of public comments, we are finalizing the inclusion of the (MIPS Q128) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan in the low back pain quality measure set as proposed at § 512.725(c)(3).

(v) Functional Status Change for Patients with Low Back Impairments (MIPS Q220)

We proposed to include the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) measure in the ASM low back pain quality measure set. This measure would encourage ASM participants to adopt a more patient-centered and holistic approach to improving functional status and quality of life in patients with low back pain. As a patient-reported outcome measure, the measure tracks changes in a patient's functional status over time, assessing changes and rewarding meaningful improvement with a better measure score for the ASM participant. We believe measuring and improving functional status could increase self-efficacy, improve financial well-being, and lower future medical costs. Measuring a change in functional status can also be used to direct and assess the success of treatment. Furthermore, the adoption of validated objective measurements may enhance the reliability and sensitivity of detecting physical deficits or monitoring posttreatment improvements of low back pain in older adults.[230] Notably, relevant professional organizations and specialty societies recommend the use of

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[229] 2025 MIPS Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan Measure Specifications. https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2025_Measure_128_MIPSCQM.pdf

[230] Wong AY, Karppinen J, Samartzis D. Low back pain in older adults: risk factors, management options and future directions. *Scoliosis and Spinal Disorders*. 2017;12(1):1-23. doi:https://doi.org/10.1186/s13013-017-0121-3.

functional status surveys to assess and monitor changes in low back pain over time. The American Academy of Orthopaedic Surgeons recommends the use of the Oswestry Disability Index, which can be used to fulfill this measure, as one of its preferred tools for spine care. While AAOS also recommends the Neck Disability Index, it is less relevant to ASM.[231,232] These functional status surveys include questions related to modifiable lifestyle factors, such as physical activity and social isolation, prompting conversation with patients that can prevent the worsening of comorbid conditions and low back pain. In addition, this measure aligns with other quality programs, such as the Rehabilitative Support for Musculoskeletal Care MVP in the Quality Payment Program and the Core Quality Measures Collaborative Orthopedics set. By holding ASM participants who treat low back pain accountable for this measure, ASM promotes a comprehensive approach to low back pain management, including appropriate assessment, treatment, and monitoring of changes. We sought comment on our proposal to include the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) measure in the low back pain quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support the proposed inclusion of MIPS Q220: Functional Status Change for Patients with Low Back Impairments in the ASM low back pain quality measure set, noting concerns that while Focus on Therapeutic Outcomes, Inc (FOTO) permits free access to components of the measure, the website's functionality is not interoperable with clinicians' chosen health IT systems and leading to a disjointed and labor intensive manual process, requiring the licensed FOTO's tools to report measure data and increasing reporting burden and costs for both clinicians and vendors. The commenters expressed concern that it could disadvantage small or rural practices due to limited or no access to FOTO's systems. The commenters noted that CMS should consider only including eCQMs in ASM and recommended that CMS should wait until an eCQM has been developed for the measure. A few commenters did not support the measure, noting its reliance on the FOTO Low Back Functional

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[231] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.
[232] Performance Measures by Orthopaedic Subspecialty. Aaos.org. Published 2025. Accessed April 23, 2025. https://www.aaos.org/quality/research-resources/patient-reported-outcome-measures/performance-measures-by-orthopaedic-subspecialty.

Status PRO-PM. A commenter expressed concerns with the risk-adjustment algorithm, noting it is proprietary and undisclosed, restricting clinicians to replicate or validate results. Another commenter noted that the FOTO Low Back Status PRO-PM tool is not used by neurosurgeons, who instead commonly use tools such as the Oswestry Disability Index. A few commenters expressed concern regarding the measure's reliability and validity as it was last reviewed for endorsement maintenance in 2019. The commenters also shared their concern that the measure was originally developed to evaluate quality of care for physical therapists, chiropractors, and other nonphysician practitioners, who are excluded from ASM. The commenters also expressed concern that the measure focuses primarily on rehabilitation services rather than care provided by other specialties, such as neurosurgery. They also noted that these specialties may need to interface with a new system outside of their usual workflows and EHRs to report data for this measure. A few commenters also noted that the measure is defined using a different set of diagnosis codes than those used for the Low Back Pain EBCM. A few commenters noted that the measure relies on the FOTO Low Back Patient-Reported Outcome tool, and it is not clear whether this survey aligns with the Oswestry Disability Index, which is referenced in the measure's justification. A commenter noted that it requires both the initiation and completion of a functional status episode within a single calendar year, while care episodes for low back pain often span multiple calendar years. Another commenter noted that the measure is not reported in significant numbers by certain specialists, specifically anesthesiologists. Another commenter recommended that CMS should not include any patient reported outcome measure that is beyond a clinician's control. A commenter shared their belief that low back pain patients may require more than 180 days for meaningful improvement, based on disease severity and comorbidities, and recommended that the measure timeframes appropriately account for these factors.

Response: We appreciate the comments regarding burden and concerns related to the survey tools for functional status assessment in low back pain patients under MIPS Q220: Functional Status Change for Patients with Low Back Impairments. We understand the operational challenges raised by commenters regarding system interoperability and the potential impact on smaller practices and believe our flexibility for small practices to report quality measures in the quality ASM performance category at the TIN-level, as further described in section III.C.2.d.(1).(b)., help address this concern. We chose not to restrict the

measure to eCQMs specifically to allow greater flexibility to participants in selecting appropriate assessment tools that best fit their practice workflows and patient populations. While we acknowledge the concerns about FOTO's system integration challenges, the measure allows multiple validated survey instruments to satisfy reporting requirements, so it is not limited solely to FOTO tools. The Oswestry Disability Index, which several commenters noted as commonly used by neurosurgeons, is an appropriate and accepted tool under this measure's specifications. This flexibility in tool selection addresses many of the commenters' concerns about being restricted to a single proprietary system.

We believe this measure and the tools included are clinically appropriate and methodologically sound, given their established use in MIPS and their demonstrated validity in assessing patient functional status and promoting clinical improvement. The measure has undergone rigorous evaluation processes, and while the last formal endorsement review was in 2019, we believe the underlying clinical principles and measurement approaches remain current with accepted standards of care for functional assessment in low back pain management. Regarding concerns that the measure was originally developed for rehabilitation services, we believe the measure's focus on functional improvement is relevant across specialties, as neurosurgeons, anesthesiologists, and other specialists all contribute to patients' functional recovery, even if through different intervention modalities.

By requiring this measure in ASM, we ensure that functional status outcomes are reported adequately and allow for like-to-like comparisons across ASM participants and specialties. This standardized approach is essential for meaningful quality assessment and improvement initiatives. The model's five-year test period provides sufficient time for patient improvement to be reflected year-to-year or over the model’s five-year duration, which would accommodate the longer recovery timelines that some commenters noted may be necessary for complex low back pain cases. Regarding concerns about episodes spanning multiple calendar years, the measure methodology accounts for these clinical realities while maintaining the integrity of annual reporting cycles. For specialists who may not currently report this measure in significant numbers, ASM provides an opportunity to establish baseline performance and drive improvement in functional outcome assessment across all participating specialties. The inclusion of patient-reported outcome measures reflects our commitment to patient-centered care and recognizes that functional improvement is a critical indicator of treatment success that should be within the influence of

all ASM participants, regardless of their specific intervention approach.

Comment: A few commenters offered recommendations on the proposed inclusion of MIPS Q220: Functional Status Change for Patients with Low Back Impairments in the ASM low back pain quality measure set. A commenter recommended that CMS work with the measure steward to improve ease of access and interoperability for clinicians and HIT vendors to program the necessary measure components into their systems. The commenter also recommended re-specifying the measure to remove the FOTO Lumbar PRO-PM and instead use an alternative modern measurement science-based PRO-PM that has fewer proprietary restrictions on interoperability and use within HIT systems, such as the PROMIS Physical Function or the PROMIS Pain Interference. A commenter recommended CMS to clarify the measure specifications as the proposed rule language references the use of Oswestry Disability Index instead of the Modified Oswestry Disability Index for the MIPS Q220 measure, noting concerns that these versions are not interchangeable. Another commenter shared their belief that clinicians not currently using FOTO-supported platforms may face technical and operational challenges in adopting the measure which may introduce complexity in terms of governance, licensing, and implementation and recommended that CMS clarify whether it intends to reconfigure the measure into a PRO-PM; how it plans to engage with non-CMS measure stewards ; and the timeline and process for testing and validation.

Response: We appreciate the recommendations regarding the inclusion of MIPS Q220: Functional Status Change for Patients with Low Back Impairments in the ASM low back pain quality measure set. We believe the January 1st, 2027 start date should provide adequate lead time for participants to update their systems, enhance their measure reporting capabilities, and work with their vendors as needed.

While we appreciate the recommendations for changing measures or re-specifying to use alternative PRO-PMs such as PROMIS Physical Function or PROMIS Pain Interference, we will adhere to the existing MIPS specifications to ensure alignment with MIPS, thereby reducing burden caused by model-specific measures and specifications. The latest specifications for the MIPS Q220 measure should be referenced as the source of truth for which survey instruments are appropriate. Importantly, the MIPS Q220 measure includes the FOTO Low Back Functional Status PROM/FOTO Public Access Survey, which is available free of charge for use in individual clinical practice. Additionally, there is a validated

crosswalk available from the Modified Oswestry Disability Index for participants who prefer to use this alternative tool, which has been tested for reliability and validity.

We recognize the potential effort that further implementing this measure may introduce, but it is vital to the integrity of the model as it represents our best outcome measure available for low back pain.

These measurement activities should be occurring to ensure improvement in patient outcomes, and therefore we will include the measure in our set. We believe that the January 1st, 2027 start date and any support we may provide to enhance adoption during this period before model start will address the primary concerns raised by commenters, particularly given the availability of free tools and validated crosswalks that reduce barriers to implementation.

Comment: A few commenters supported the proposal to include the measure MIPS Q220: Functional Status Change for Patients with Low Back Impairments in the ASM measure set, noting that tracking and assessing a patient's functional status over time is a patient-centered way to reward meaningful improvement for ASM participants. A commenter specifically noted several advantages of the measure, including its non-condition-specific design, allowing clinicians to select validated measures appropriate to their clinical workflows; established implementation in EHRs and registries, reducing technical and operational burden; and alignment with existing quality initiatives, making it easier for providers to integrate into current reporting structures.

Response: We appreciate the support and feedback regarding the inclusion of MIPS Q220: Functional Status Change for Patients with Low Back Impairments in the ASM measure set. We are pleased that commenters recognize the patient-centered value of tracking functional status over time as a meaningful way to reward improvement for ASM participants.

The advantages highlighted by commenters reinforce our belief that this measure will enhance care delivery within ASM and beyond, focusing on prevention and functional status improvement that directly benefits patients with low back pain.

After consideration of public comments, we are finalizing the inclusion of the MIPS Q220: Functional Status Change for Patients with Low Back Impairments in the low back pain quality measure set as proposed at § 512.725(c)(4).

We also received broad feedback regarding the low back pain quality measure set. The following

is a summary of the comments we received and our responses

Comment: Several commenters expressed concerns about the proposed inclusion of proprietary measures in ASM that are controlled by private vendors, rely on non-transparent instruments or risk adjustment methods. A commenter expressed concern that requiring measures with proprietary dependencies undermines transparency, equity, and scalability and conflicts with CMS' own standards to avoid measures with misleading or inaccurate results. Another commenter recommended that the proposed ASM measures must be transparent, reproducible, and broadly accessible and that CMS should not use measures that are dependent on closed tools or private algorithms. The commenters specifically highlighted the proposed measures MIPS Q220: Functional Status Change for Patients With Low Back Impairments and MIPS Q503: Patient Activation Measure (PAM) as proprietary measures and recommended that CMS remove these measures from the ASM low back pain quality measure set unless all PRO-PM items, scoring rules, and risk-adjustment models are fully disclosed and publicly available. A commenter also recommended that if these measures are finalized, CMS should permit alternatives or substitutions with open measures of functional status and patient engagement supported in certified health IT. Another commenter recommended that CMS prioritize validated, accessible tools that do not require licensing fees, such as the Modified Oswestry Disability Index or the PROMIS Global-10.

Response: We appreciate the feedback on the proprietary nature of some measures. We would like to note that MIPS Q220: Functional Status Change for Patients With Low Back Impairments, while it uses a proprietary tool, has a version of the tool available free of charge for individual clinical practices. The survey tool used by the measure also includes a free crosswalk from the Modified Oswestry Disability Index, addressing concerns related to the ability to use multiple validated instruments.

Additionally, we are not including PAM measures in the final ASM measure set, so the proprietary nature of this measure is not an issue for the model. We believe we have included only measures that make the most clinical sense and create a holistic view of a participant's care furnished to patients. We also believe these measures will help promote improvement in certain areas, such as comorbid conditions related to low back pain.

Regarding alternatives, we purposefully created a mandatory set of measures in ASM that all participants will report. This will enable like-to-like comparison and accountability for the same

activities. This standardized approach ensures consistent quality measurement across all ASM participants while maintaining the clinical integrity of the model.

Comment: Several commenters generally expressed their support for the proposed ASM low back pain quality measure set. The commenters shared their belief that the proposed measure set aligns with modern, evidence-based guidelines, focuses on promoting high-value care by discouraging the use of low-value imaging, fostering patient-centeredness by incorporating the patient's voice through patient-reported outcome performance measures (PRO-PMs), promoting functional status and patient self-efficacy, and drawing attention to impactful co-factors, such as depression, that should be clinically managed to help achieve optimal chronic low back pain outcomes. A commenter specifically supported the proposed PRO-PMs, noting that they elevate patient voice and incentivize clinicians to be more responsive to the treatment outcomes.

Response: We appreciate the strong support for the proposed ASM low back pain quality measure set. We are encouraged that interested parties recognize the alignment with evidence-based guidelines and the focus on high-value care delivery.

Comment: Several commenters recommended that CMS include other quality measures in the ASM low back pain quality measure set. A few commenters recommended that CMS adopt functional-status PRO-PMs for low back pain with remote capture, such as the PROMIS Physical Function or Oswestry Disability Index for low back pain functional outcomes. A commenter specifically stated that remote PRO-PMs reduce documentation burden, improve completion rates, and are more equitable for beneficiaries with mobility or transportation barriers. The commenter also recommended that CMS recognize FHIR-enabled, application-based PROMIS capture and acceptance of patient-entered data into certified EHRs which aligns with ASM's interoperability aims. A commenter recommended that CMS adopt and re-specify the MSK-3 measure for this measure set, noting that the MSK-3 measure utilizes PROMIS Pain Interference, which would offer significant benefits, such as enabling cross-cutting comparability of results across diverse patient populations and care settings that are not limited solely to low back pain. The commenter shared their belief that this measure is an outcome measure, may result in better performance than a process measure, would reduce patient response burden while maintaining optimal reliability and validity through use of existing “short-form” versions. Another commenter

recommended that CMS include a measure on physical therapy referrals to incentivize access to high value services for patients with low back pain. The commenter noted that the measure would decrease the use of more costly, low-value, testing and interventions such as imaging, injections surgery, and opioids, reduce the overall cost of managing low back pain, and improve patient outcomes. A few commenters recommended that CMS include measures to assess lifestyle interventions. A commenter recommended measures on pain management effectiveness and care coordination. Another commenter recommended that CMS use the CAHPS for MIPS survey to better measure patient experience and capture domains, such as patient communication, care coordination, and shared decision-making.

Response: We appreciate these recommendations for additional quality measures in the ASM low back pain quality measure set. We have carefully considered these measures during model development and decided that the current proposed set represents the best approach to target the condition specifically, minimize burden on providers, support alignment with other CMS programs, and achieve our broader model objectives.

Several of the general domains recommended by commenters are already covered by our measures in different but effective ways. For example, our inclusion of MIPS Q220: Functional Status Change for Patients with Low Back Impairments addresses the functional status outcomes that commenters sought through PROMIS Physical Function or Oswestry Disability Index measures, while maintaining alignment with existing MIPS specifications. This measure captures patient-reported functional improvements over time, which is fundamental to assessing the effectiveness of low back pain treatment.

The patient experience domains highlighted by commenters, including patient communication, care coordination, and shared decision-making are integral to the patient-reported outcome measures we have included and will be further supported through the model's emphasis on care coordination and patient engagement activities. We believe our overall ASM measurement approach, which combines targeted quality measures with improvement activities and cost accountability, will effectively meet the goals of promoting high-value, patient-centered care while reducing the administrative burden on ASM participants.

While we recognize the potential benefits of remote PRO-PM capture and FHIR-enabled

applications, our current approach balances innovation with implementation feasibility during the model's initial years. We will continue to evaluate opportunities to enhance our measurement approach as health IT capabilities evolve and as we gain experience with the model's implementation.

Comment: Many comments generally expressed concern about the proposed ASM low back pain quality measure set. A few commenters shared their concern that many of the proposed measures were designed for therapists, chiropractors, and other non-physician practitioners and are not reflective of the specialties included in the ASM low back pain cohort, such as physiatry, surgery or anesthesiology. A commenter expressed concern that anesthesiologists have a limited set of relevant quality measures in MIPS and further noted that the proposed measures in the ASM low back pain cohort are either not top-performing or not commonly used by anesthesiologists. A few commenters also shared their belief that the proposed measures would not appropriately assess whether Medicare beneficiaries with low back pain achieve better outcomes, reflect quality of care provided to patients, or protect patients from underuse caused by efforts to reduce spending. A few commenters shared their concern that none of the proposed quality measures are included in the MIPS Neurosurgery Specialty Set or the MIPS Orthopedic Specialty Set. A few commenters also expressed concern that the ASM low back pain quality measure set is skewed to focus more heavily on a reduction of services and does not include enough patient-reported outcome measures to assess quality of life, functional status, and patient-clinician relationships. A few commenters shared their concern that the proposed measures would focus on younger patients and all-payer patients rather than being limited to Medicare patients. A commenter noted that the measures would not be relevant to ASM participants' practices or the care they provide. Another commenter noted that the proposed measure set relies heavily on process-based measures and quality measures that would not foster holistic, patient-centered improvements in care. A commenter also expressed concern that ASM quality measures may discourage clinicians from treating high need individuals with complex or severe low back pain and may add complexity to determine ASM financial incentives relevant to outcomes.

Response: We appreciate the feedback regarding the proposed ASM low back pain quality measure set. We are limited by which measures are available and validated for the specialists included in the model, and we believe the selected measures are appropriate for assessing quality care delivery for patients with low back pain, for multiple specialties. All-payer measures provide valuable insights into

care quality across diverse patient populations and payer types, which enhances the robustness and generalizability of our quality assessment approach. We aimed for alignment with MIPS and MVPs in many areas to reduce administrative burden and maintain consistency across CMS quality programs, while also focusing on the measures most pertinent to low back pain management and outcomes.

We include a low back pain patient-reported outcome measure (PRO-PM) which is a strong tool for understanding functional outcomes and patient-centered results that matter most to beneficiaries. This measure directly addresses concerns about assessing quality of life, functional status, and patient experience with their care. The measures include established risk adjustment practices that should ensure scoring is equitable across different patient populations and practice settings, and these adjustments are designed to prevent practices from turning away patients with complex conditions or higher severity. Our measure set balances process and outcome measures to provide a comprehensive assessment of care quality while maintaining feasibility for specialty providers participating in ASM. We believe this targeted approach will effectively assess whether Medicare beneficiaries with low back pain achieve better outcomes while supporting the delivery of high-value, patient-centered care.

Comment: A commenter recommended that CMS limit the proposed measures to patients who have been in established care for 90-plus days and exclude patients who are seeking procedural care only. A commenter recommended that CMS provide a clear set of specific diagnosis codes and definitions that will be used to determine the denominators for low back pain measures, which should include a look back period of no more than 2 years. A commenter expressed concern that applying the proposed efficiency adjustment to rehabilitative therapy codes may impact patients with low pain. A commenter recommended that CMS ensure CPT codes and coverage for therapies, such as aquatic therapy, massage therapy, and other non-medication, non-procedural treatments, which are vital for patients with low back pain.

Response: We appreciate the commenters for the feedback regarding the ASM low back pain quality measures and related concerns. We are aligning quality measures with the existing inclusion criteria for each measure that has been thoroughly reviewed for validity. Furthermore, adjusting the measure specifications would present a significant burden to practices that already report some of the same quality measures in MIPS. We refer readers to the publicly available measure specifications to

determine details on diagnosis codes for denominators, as these specifications provide comprehensive information about the specific codes and definitions used for each measure. ASM does not have a proposed adjustment to rehabilitative therapy codes, as the model focuses on quality measurement and cost accountability rather than modifying existing payment structures for specific service categories. ASM does not change which services are covered under Medicare, so all therapies typically covered for patients continue to be available to beneficiaries. The model's focus is on improving the quality and efficiency of care delivery while maintaining access to the full range of appropriate treatment options for patients with low back pain.

Comment: A few commenters recommended the use of objective pain data and databases for measurement in the ASM low back pain cohort. The commenters shared their belief that CMS would need access to existing objective pain databases in order to measure an individual's pain objectively and ensure cost-effective care. A commenter shared their belief that pain data would provide specialists with proper metrics to help guide the patients' care journey, reduce avoidable hospitalizations, and provide the right level of care to a patient. The commenters further shared their belief that pain data can allow patients to be screened more effectively for coordinated care and be used as an outcome measure to assess improvement after a procedure or surgery, noting that incorporating pain data into healthcare practice would align with ASM goals and contribute to improved outcomes for Medicare beneficiaries with low back pain.

Response: We appreciate commenters' feedback regarding the use of objective pain data and databases for measurement in the ASM low back pain cohort. We believe that our patient-reported outcome measure (PRO-PM) focused on functional status will help meet these goals of providing meaningful metrics to guide patient care and assess treatment effectiveness. We currently do not have an appropriate way to incorporate pain databases into the model without creating undue burden and operational complications for participants. However, ASM participants can engage in these activities if they find them clinically meaningful and beneficial for their patient care, as part of their broader quality improvement efforts. We appreciate the recognition that pain measurement aligns with ASM goals, and we believe our functional status PRO-PM will capture important patient-centered outcomes that reflect the effectiveness of low back pain treatment while maintaining feasibility for widespread implementation.

Comment: A commenter recommended that CMS prioritize interested parties' feedback in measure selection for ASM measure sets. The commenter suggested that CMS collect patient feedback prior to finalizing measure sets as it is essential to creating meaningful measure sets. A commenter also recommended that CMS explore mechanisms to account for primary care influence in quality metrics.

Response: We appreciate the commenter for the feedback regarding interested party input and patient feedback in measure selection for ASM measure sets. We ensure that patient voice and whole person's health is accounted for in our measure set design and development process. We believe that including a PROM in each measure set helps to ensure the patient's perspective is heard and valued in quality assessment. We also received input from several entities during the measure development process, including those that represent beneficiary feedback and patient advocacy perspectives. This interested parties' engagement was essential to creating meaningful measure sets that reflect both clinical excellence and patient-centered care priorities. Our improvement activities strategy is focused on primary care engagement and collaboration, and that should be reflected in the model through this mechanism. These activities are designed to promote coordination between specialty care providers and primary care teams, ensuring that patients receive comprehensive, well-coordinated care that addresses their full range of health needs rather than focusing solely on the specialty condition being managed under ASM.

After consideration of public comments, we are finalizing the inclusion of the (MIPS Q220) Functional Status Change for Patients with Low Back Impairments in the low back pain quality measure set as proposed at § 512.725(c)(4).

(d) Other Measures Under Consideration

(i) Patient Activation Measure (PAM) (MIPS Q503)

We sought comments on whether the Patient Activation Measure (PAM) (MIPS Q503) would be appropriate to include in both the heart failure and low back pain quality measure sets. Chronic conditions, in general, are influenced by external factors, such as lifestyle, education, nutrition, and activity. Patient activation, which refers to a patient's knowledge, skills, and confidence in managing their health condition, is an important factor in achieving better health outcomes and adherence to treatment plans. For chronic conditions, such as heart failure and low back pain, where self-management and active patient engagement are crucial, assessing and improving patient activation levels could help ASM

participants tailor their ability to provide more patient-centered support and education. Including the PAM measure in ASM could incentivize clinicians to prioritize strategies that enhance patient activation, such as shared decision-making, goal setting, and self-management support.[233] Furthermore, higher levels of patient activation have been associated with better health behaviors, such as physical activity, and improved mental health outcomes.[234] We are concerned by the burden on participants and patients that may be introduced by: (1) adding an additional measure to the set, (2) using a patient survey measure, and (3) PAM being a proprietary measure. We seek comments on whether PAM could be applicable to the heart failure and low back pain quality measure sets.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed inclusion of MIPS Q503: Patient Activation Measure (PAM) in the ASM quality measure set. These commenters noted that this measure is a valuable outcome measure that can help predict and assess health, utilization, and cost. They believed that this measure would help patients become more empowered and engaged in their care, improve self-management skills, and promote shared decision-making between patients and clinicians. A few commenters stated their belief that the measure has been used in various and diverse settings, including the Kidney Care Choices Model, to understand risk, support disease management and care, allocate resources, and improve equity. A few commenters stated that PAM is the only validated tool that comprehensively assesses patients' knowledge, skills, and confidence in managing their health that has been endorsed by the Consensus-Based Entity. A few commenters also noted that the PAM imposes minimal operational burden relative to its value in clinical care and that it would provide CMS with a parsimonious and consistent measurement approach across model cohorts and other quality programs. Specifically, a commenter noted that the measure addition would be offset by the expected relatively low volume of qualifying episodes, which will result in a smaller eligible survey population and therefore reduce reporting burden. A few commenters addressed CMS' concerns about the PAM being a

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[233] Newland P, Lorenz R, Oliver BJ. Patient activation in adults with chronic conditions: A systematic review. *Journal of Health Psychology*. Published online August 23, 2020:135910532094779. doi:https://doi.org/10.1177/1359105320947790.
[234] Hosseinzadeh H, Downie S, Shnaigat M. Effectiveness of health literacy- and patient activation-targeted interventions on chronic disease self-management outcomes in outpatient settings: a systematic review. *Australian Journal of Primary Health*. 2022;28(2). doi:https://doi.org/10.1071/py21176.

proprietary measure and stated that CMS uses other proprietary measures in various other reporting programs. A few commenters also noted that inclusion of the measure would provide CMS with a more complete view of patient capacity, complementing rather than duplicating functional status measures. They also stated that the measure enables clinicians to tailor education and support individual patient needs. A commenter recommended that CMS should not focus so heavily on reporting burden and that CMS could reduce the burden of the PAM by removing other proposed quality measures while another commenter noted that the PAM is aligned with the CMS Innovation Center 2025 Strategy to Make America Healthy Again.

Response: We appreciate the thoughtful comments that supported the inclusion of MIPS Q503: Patient Activation Measure (PAM) in the ASM quality measure set. We recognize the value that commenters see in PAM as a tool for assessing patient engagement, self-management skills, and shared decision-making capabilities.

While we acknowledge the benefits highlighted by commenters, we believe that adding an additional survey instrument that is not directly tied to low back pain would weaken our focused measure set and introduce unnecessary reporting burden. Our goal is to maintain a streamlined, clinically relevant measure set that directly addresses the specific conditions and outcomes most important to the ASM cohorts.

We want to emphasize that many of the patient engagement and empowerment benefits noted by commenters regarding PAM will be addressed in part by ASM's improvement activities and care coordination requirements. These activities focus on reducing care fragmentation for patients, improving collaboration between providers, and enhancing communication with patients. Additionally, ASM’s improvement activities performance category includes health-related social needs screening requirements, which can promote valuable conversations between providers and patients and address some of the same patient engagement aspects as PAM while being relevant and actionable for the clinical conditions being managed.

Comment: Several commenters did not support the proposed inclusion of the MIPS Q503: Patient Activation Measure (PAM) because they believed it would increase burden since patients would have to respond to ten or more questions and be difficult to implement. A commenter noted that CMS should wait

until data collection is more feasible and more resources are available to practices to implement the measure. Another commenter believed that smaller practices may lack the survey administration, longitudinal tracking, and analytic infrastructure needed to implement the measure. They also noted that scoring and submission complexities of the measure may further disadvantage resource-limited providers. Another commenter did not support the measure, because they believed it was not tested at the individual clinician level (TIN/NPI) and that the measure requires too many patients to meet the minimum reliability level. Additionally, a commenter recommended utilizing the four-question version of the PROMIS Self-Efficacy measure, which they believe is more accessible and interoperable than the PAM. A commenter did not support the measure, because it has not been validated in spine care or for chronic pain populations and recommended CMS conduct a pilot of PAM in ASM to assess feasibility and clinical utility before requiring widespread adoption.

Response: We appreciate commenters for their thoughtful feedback regarding the proposed inclusion of MIPS Q503: Patient Activation Measure (PAM) in the ASM quality measure set. We agree with the concerns raised by commenters about implementation burden and added survey administration challenges for smaller practices, and are finalizing the exclusion of the PAM measure from ASM. Our decision aligns with our goal of implementing a focused, clinically relevant measure set that minimizes administrative burden while maintaining meaningful quality measurement.

Based on the feedback, we are not including MIPS Q503: Patient Activation Measure (PAM) in the heart failure or low back pain quality measure sets.

(ii) Advance Care Plan (MIPS Q047)

We considered including the Advance Care Plan (MIPS Q047) measure in the heart failure quality measure set. Advance care planning is important for understanding and documenting a patient's wishes regarding their medical treatment, acknowledging that wishes may evolve as circumstances and health status change. Heart failure, depending on stage and other risk factors, can progress unpredictably and rapidly. According to one meta-analysis, survival rates for all patients with heart failure are 95.7 percent at 1 month, 86.5 percent at 1 year, and 56.7 percent at 5 years, with elderly patients having

lower survival rates on average.[235] Having a documented plan in place is necessary to ensure a patient's wishes are followed should they become incapacitated and unable to make care decisions. One study of Medicare beneficiaries with severe illness found that timely advance care planning was associated with significantly less intensive end-of-life care utilization and fewer in-hospital deaths, hospital admissions, intensive care unit admissions, and emergency department visits.[236] Another study on Medicare beneficiaries with heart failure found that beneficiaries who received advance care planning visits had 19 percent lower total end-of-life expenditure compared to those who did not.[237] This measure could encourage ASM participants to have proactive discussions with their patients about end-of-life care, advance directives, and other important decisions related to their treatment plan. However, we decided not to include the measure, as we worry the measure would not result in sufficiently meaningful positive changes for patients to justify the increased burden. Also, we do not believe the cardiologist would be the most appropriate provider to oversee advance care planning in every case, and we want to avoid duplication of effort with PCPs. We seek comments on whether the Advance Care Plan measure could be meaningful if included in the heart failure quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposed inclusion of the MIPS Q047: Advance Care Plan measure, because they believed the measure is burdensome to implement and is better suited for primary care settings.

Response: We appreciate the feedback regarding the proposed inclusion of MIPS Q047: Advance Care Plan measure in the ASM quality measure set. We agree with the concerns raised by commenters about the implementation burden and the measure's suitability for specialty care settings.

Comment: A commenter supported the proposed inclusion of the MIPS Q047: Advance Care Plan measure because they believed that the measure would result in meaningful positive changes for patients

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[235] Jones NR, Roalfe AK, Adoki I, Hobbs FDR, Taylor CJ. Survival of patients with chronic heart failure in the community: A systematic review and meta-analysis. *European Journal of Heart Failure*. 2019;21(11):1306-1325. doi:https://doi.org/10.1002/ejhf.1594.
[236] Weissman JS, Reich AJ, Prigerson HG, et al. Association of Advance Care Planning Visits With Intensity of Health Care for Medicare Beneficiaries With Serious Illness at the End of Life. *JAMA Health Forum*. 2021;2(7):e211829. doi:*https://doi.org/10.1001/jamahealthforum.2021.1829*.
[237] Brill SB, Riley SR, Prater L, et al. Advance Care Planning (ACP) in Medicare Beneficiaries with Heart Failure. *Journal of General Internal Medicine*. 2024;39(13):2487-2495. doi:*https://doi.org/10.1007/s11606-024-08604-1*.

which would justify any increased burden. The commenter also noted that the cardiologist is often the most appropriate provider to oversee advance care planning, since they can become the practical primary provider for patients with heart failure.

Response: We appreciate the support for including MIPS Q047: Advance Care Plan measure and the recognition of its potential value for heart failure patients. However, we are not including this measure in the ASM quality measure set. At this time, we are concerned about the implementation burden and want to keep the measure set clinically focused on the specific conditions being managed under ASM.

We believe that the activities included in the improvement activities and other elements of ASM designed to improve care coordination and patient engagement will promote important conversations like advance care planning between providers and patients. These elements can facilitate meaningful patient-provider discussions while maintaining our focus on condition-specific quality measures that directly relate to the clinical care being provided under the model.

After consideration of public comments, we are not including the MIPS Q047: Advance Care Plan measure in the heart failure quality measure set.

(iii) Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MIPS Q484)

We considered including the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MIPS Q484) measure in the heart failure quality measure set. We believe evaluating potentially preventable hospital admissions could help assess the quality of ambulatory care provided by cardiologists to patients with multiple chronic conditions, including heart failure. Nearly 90 percent of adults with heart failure have two or more additional chronic conditions, and almost 60 percent have five or more chronic conditions.[238] For heart failure patients with multiple comorbidities, reducing potentially preventable hospitalizations is a key goal for improving outcomes and reducing health care costs. While incentivizing cardiologists to adopt best practices, such as improving care coordination with primary care and enhancing self-management support, is of interest to

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[238] Dharmarajan K, Dunlay SM. Multimorbidity in Older Adults with Heart Failure. *Clinics in Geriatric Medicine*. 2016;32(2):277-289. doi:https://doi.org/10.1016/j.cger.2016.01.002.

CMS, this measure is not adequately targeted to heart failure. We also do not consider this measure appropriate for the low back pain quality measure set, as the condition is less prone to hospital admissions and re-admissions. We seek comments on whether the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MIPS Q484) measure should be considered for inclusion in the heart failure quality measure set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposed inclusion of the MIPS Q484: Admission rates for Multiple Chronic Conditions (MCC) measure and noted that while this may be a meaningful measure it does not target patients with heart failure. A commenter noted that the measure is only endorsed at the group level, and reliability testing showed results of only 0.413 for practices with at least 15 clinicians and 18 patients with multiple chronic conditions.

Response: We appreciate commenters' feedback regarding the proposed inclusion of MIPS Q484: Admission rates for Multiple Chronic Conditions (MCC) measure in the ASM quality measure set. We agree with the concerns raised by commenters and are not including this measure in the heart failure quality measure set. Our goal is to maintain a streamlined, condition-specific measure set that directly relates to the care and outcomes most relevant to heart failure management under the ASM.

After consideration of public comments, we are not including the MIPS Q484: Admission rates for Multiple Chronic Conditions (MCC) measure in the heart failure quality measure set.

(iv) Cardiac Rehabilitation Patient Referral from an Outpatient Setting (MIPS Q243)

We considered including the Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure in the heart failure quality measure set. This measure assesses the percentage of patients evaluated in an outpatient setting who have qualified for cardiac rehabilitation and were referred to an outpatient cardiac rehabilitation program. As it relates to heart failure, Medicare patients only qualify for a cardiac rehabilitation program if they have stable chronic heart failure, defined as left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks.[239] In these patients, cardiac

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[239] Cardiac Rehabilitation Program Coverage. www.medicare.gov. https://www.medicare.gov/coverage/cardiac-rehabilitation.

rehabilitation is a comprehensive intervention that includes exercise training, education, and counseling to improve cardiovascular health and reduce the risk of future cardiac events. For patients with heart failure, meta-analyses on cardiac rehabilitation have shown that it improves functional capacity, exercise duration, and health-related quality of life.[240] Also, cardiac rehabilitation programs have evolved to serve other purposes, such as disease management and prevention centers that assist with medication adherence, weight loss, smoking cessation, and other contributors to heart disease.[241] By including this measure in the heart failure quality measure set, CMS could incentivize cardiologists and other clinicians to refer eligible patients with heart failure to cardiac rehabilitation programs, which can potentially improve their long-term outcomes and reduce their risk of hospitalizations. We decided not to include the measure in the heart failure quality measure set because access to cardiac rehabilitation programs is significantly varied based on region due to factors like limited availability, density, eligibility, or distance, and these factors could negatively affect ASM participants due to no fault of their own.[242] We seek comment on whether the Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure could be meaningful if included in the heart failure quality measure set.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed inclusion of the MIPS Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure, because they believed it would incentivize cardiologists and other clinicians to refer eligible patients to cardiac rehabilitation programs that improve long-term health outcomes, thereby reducing risk of hospitalizations. A commenter recognized the challenges in access to cardiac rehabilitation programs but noted that including the measure would help close gaps in access by ensuring eligible patients are referred promptly wherever programs exist. They also recommended that CMS could exempt ASM participants from reporting the measure if they attest that cardiac rehabilitation programs are unavailable in their referral region. Another

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[240] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18). doi:https://doi.org/10.1161/cir.0000000000001063.
[241] Ades PA, Keteyian SJ, Wright JS, et al. Increasing Cardiac Rehabilitation Participation From 20% to 70%: A Road Map From the Million Hearts Cardiac Rehabilitation Collaborative. *Mayo Clinic Proceedings*. 2017;92(2):234-242. doi:https://doi.org/10.1016/j.mayocp.2016.10.014.
[242] Duncan MS, Robbins NN, Wernke SA, et al. Geographic Variation in Access to Cardiac Rehabilitation. *Journal of the American College of Cardiology*. 2023;81(11):1049-1060. doi:https://doi.org/10.1016/j.jacc.2023.01.016.

commenter supported the inclusion of the measure and also recommended that CMS consider the MIPS Q374: Closing the Referral Loop: Receipt of Specialist Report measure. The commenters also requested that an eCQM equivalent be made available. Another commenter recommended that CMS include this measure as an optional measure or improvement activity given its strong clinical value and evidence base.

Response: We appreciate the support expressed by commenters for including MIPS Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure and understand the clinical value they see in promoting cardiac rehabilitation referrals. We recognize that cardiac rehabilitation can provide significant benefits for eligible heart failure patients by improving long-term health outcomes and potentially reducing hospitalizations. However, after careful consideration of the feedback and operational realities, we have decided not to include this measure in the ASM heart failure quality measure set at this time. While cardiac rehabilitation is clinically appropriate in some cases of heart failure, it is not indicated for all heart failure patients, and persistent barriers to access across different geographic regions would disadvantage providers where these programs are not readily available. This creates challenges in establishing a universally applicable measure for ASM participants. The proposed attestation mechanism would introduce significant operational burden and administrative complexity that conflicts with our goal of streamlining quality measurement under ASM. We are committed to establishing a cohesive set of measures that nearly all ASM participants can meaningfully report on, ensuring fair and consistent evaluation across the model. While we cannot include this measure as a formal quality measure or improvement activity within the ASM framework, the overall value-based structure of ASM will naturally incentivize the use of cardiac rehabilitation where it is clinically reasonable and appropriate for patient care.

Comment: A few commenters did not support the proposed inclusion of the MIPS Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure. Commenters agreed with CMS' concerns pertaining to access challenges and regional variation in the availability of cardiac rehabilitation services. They highlighted the importance of increasing access to cardiac rehabilitation for Medicare patients before including this measure. A few commenters noted that some payers do not cover cardiac rehabilitation services. A commenter believed that access to cardiac rehabilitation is limited, because nurse practitioners are not authorized to refer patients to these services.

Response: We acknowledge commenters' feedback regarding the proposed inclusion of MIPS Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure. We agree with the concerns about access challenges and regional variation in the availability of cardiac rehabilitation services, and we are finalizing the exclusion of this measure from the measure set.

We recognize the importance of addressing barriers to cardiac rehabilitation access, including coverage limitations by some payers and authorization restrictions for nurse practitioners, before implementing quality measures that depend on these services. The regional disparities in program availability would create inequitable reporting conditions for ASM participants, which conflicts with our goal of establishing fair and consistent quality measurement across the model.

After consideration of public comments, we will not include the MIPS Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure in the heart failure quality measure set.

(v) Falls: Plan of Care

We considered including the Falls: Plan of Care measure in the low back pain quality measure set. This measure assesses the percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months. The implementation of a falls plan of care for this population could address multiple aspects of patient safety and functional improvement. Such a plan may include assessment of environmental hazards, evaluation of medication side effects, and implementation of appropriate exercise interventions to improve strength, balance, and coordination.[243] For low back pain patients specifically, the plan could incorporate targeted exercises that not only address fall prevention but also support their primary condition management, creating a comprehensive approach to their care. The Falls: Plan of Care quality measure is particularly relevant for the low back pain patient population as these patients may experience altered biomechanics, decreased mobility, and impaired balance, which may significantly increase their risk of falls. Patients with low back pain may also exhibit protective movement patterns and altered postures that, while intended to minimize pain, may compromise their stability and balance. Studies have shown that some elderly patients with a recent

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[243] CDC. Outpatient Care- STEADI in Primary Care. STEADI - Older Adult Fall Prevention. Published May 16, 2024. https://www.cdc.gov/steadi/hcp/clinical-resources/outpatient-care.html.

history of back pain are at increased risk for falls, with that risk increasing as the number of locations they experience pain in their back increases.[244,245] Another study found that community-dwelling older adults with chronic pain generally, such as low back pain, were more likely to have fallen in the past 12 months and to fall again in the future.[246] Additionally, low back pain patients may take medications such as muscle relaxants, anti-depressants, or other medications that can affect their balance and coordination, further elevating their fall risk.[247,248] By including this measure in the low back pain quality measure set, we could promote ASM participants to assess the risk a patient is at for falls and implement any needed plan or corrective actions to mitigate the issues that may be present. We decided not to propose to include the measure in the low back pain quality measure set as we are concerned that beneficiaries in ASM may have falls may for reasons, such as syncope, that are less relevant to the care of the ASM participant, and that the incidence of falls is not high enough in this patient population. We sought comments on whether the Falls: Plan of Care measure could be meaningful if included in the low back pain quality measure set.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposed inclusion of the Falls: Plan of Care measure. These commenters believed that patients may be at risk of falls for reasons unassociated with the care provided by ASM participants and that the measure appears to be topped out according to 2022 Quality Payment Program data.

Response: We appreciate the comment regarding the proposed inclusion of the Falls: Plan of Care measure. We agree that it is not the most applicable or appropriate measure for the low back pain quality measure set, particularly given the concerns raised about patients being at risk of falls for reasons unassociated with the care provided by ASM participants. We believe that other activities promoted in the

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[244] Marshall LM, Litwack-Harrison S, Makris UE, et al. A Prospective Study of Back Pain and Risk of Falls Among Older Community-dwelling Men. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*. Published online November 16, 2016:glw227. doi:https://doi.org/10.1093/gerona/glw227.

[245] Marshall LM, Litwack-Harrison S, Cawthon PM, et al. A Prospective Study of Back Pain and Risk of Falls Among Older Community-dwelling Women. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*. 2016;71(9):1177-1183. doi:https://doi.org/10.1093/gerona/glv225.

[246] Stubbs B, Binnekade T, Eggermont L, Sepehry AA, Patchay S, Schofield P. Pain and the Risk for Falls in Community-Dwelling Older Adults: Systematic Review and Meta-Analysis. *Archives of Physical Medicine and Rehabilitation*. 2014;95(1):175-187.e9. doi:https://doi.org/10.1016/j.apmr.2013.08.241.

[247] Park H, Satoh H, Miki A, Urushihara H, Sawada Y. Medications associated with falls in older people: systematic review of publications from a recent 5-year period. *European Journal of Clinical Pharmacology*. 2015;71(12):1429-1440. doi:https://doi.org/10.1007/s00228-015-1955-3.

[248] Castillo S. Inappropriate Use of Skeletal Muscle Relaxants in Geriatric Patients. Uspharmacist.com. Published January 21, 2020. Accessed April 17, 2025. https://www.uspharmacist.com/article/inappropriate-use-of-skeletal-muscle-relaxants-in-geriatric-patients?utm_source=TrendMD&utm_medium=cpc&utm_campaign=US_Pharmacist_TrendMD_0.

improvement activities performance category would address concerns in this area and help reduce falls and other adverse events through comprehensive care coordination and addressing adjacent social needs.

Comment: A few commenters supported the proposed inclusion of the Falls: Plan of Care measure. These commenters noted that this measure would encourage clinicians to systematically assess patient fall risk and implement corrective actions to mitigate those risks. Regarding CMS' concerns that falls in the ASM population may occur for reasons less directly related to their musculoskeletal condition, the commenters noted that older adults with a history of back pain are at significantly higher risk of falls. A commenter specifically recommended replacing the proposed respecified MRI Lumbar Spine for Low Back Pain measure with the Falls: Plan of Care measure.

Response: We appreciate the support expressed by commenters for the Falls: Plan of Care measure and recognize the clinical rationale regarding fall risk assessment for older adults with back pain. However, we are not including this measure in the ASM measure set to maintain a targeted and focused measure set specifically designed for low back pain management. We will not be replacing the proposed MRI Lumbar Spine for Low Back Pain measure with the Falls measure, as we are focused on including a utilization-based measure to identify and discourage low-value care. We believe that the improvement of activities and care coordination requirements within ASM will provide opportunities for participants to address broader patient safety concerns, including fall risk, through their overall patient management approach.

After consideration of public comments, we will not include the Falls: Plan of Care measure in the low back pain quality measure set.

(e) Removal and Addition of Quality Measures

While we do not plan to add or remove measures from either cohort's measure set during the ASM test period, there may be circumstances in which it is necessary. We proposed at § 512.725(d) that we would add or remove any quality measure for an ASM cohort through notice-and-comment rulemaking.

We may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. Because the quality measures currently proposed are all part of MIPS,

any updates CMS applies to the measures within MIPS would be incorporated into the quality measure sets accordingly.

We solicited comments on the proposed approach for removal or addition of quality measures.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported removing quality measures from the ASM quality measure set through notice-and-comment rulemaking and agreed with the overall desire to keep a consistent and stable set of measures. A few commenters believed it is important to have mechanisms in place to add or remove measures to adjust for advances in evidence and changes in practices that may make measures no longer meaningful and believed rulemaking was the appropriate mechanism. A commenter recommended that CMS avoid removing quality measures without a clear rationale and to maintain metrics that reflect long-term function, quality of life, and patient experience.

Response: We appreciate the supportive feedback regarding our proposed approach to quality measure maintenance in the ASM quality measure set through notice-and-comment rulemaking. We agree that rulemaking provides the appropriate level of transparency, interested parties engagement, and deliberative process for making changes to quality measures that affect ASM participants. We take seriously the recommendation to avoid removing quality measures without clear rationale and are committed to maintaining metrics that meaningfully reflect long-term function, quality of life, and patient experience. Any future proposals to modify the ASM quality measure sets will include comprehensive justification based on clinical evidence, measure performance data, interested parties feedback, and alignment with the model's objectives. We believe the notice-and-comment rulemaking process provides the appropriate framework to achieve the right balance between measure stability and the flexibility needed to ensure our measures remain clinically relevant.

Comment: A commenter did not support removing quality measures from the ASM quality measure set through notice-and-comment rulemaking and believed that maintaining a stable set of measures for 5 years and limiting submission options would restrict the ability of participants to adapt to evolving clinical standards and provide comprehensive, evidence-based care.

Response: We appreciate the feedback regarding our proposed approach to quality measure

maintenance through notice-and-comment rulemaking. However, we believe that maintaining a stable set of measures for all ASM performance years within the ASM model test period is essential to provide participants with predictability and allow them to make meaningful investments in quality improvement initiatives. The notice-and-comment rulemaking process ensures appropriate transparency and interested parties' engagement when changes to the measure set are warranted based on significant advances in clinical evidence or practice standards. We do not agree that this approach would restrict participants' ability to provide comprehensive, evidence-based care, as the measures are designed to promote high-quality, evidence-based practices within the specialty care settings. The stability of the measure set will allow participants to focus their efforts on improving performance rather than continuously adapting to changing measurement requirements.

Comment: A commenter supported removing measures from scoring if the data are compromised by external errors (for example, code omissions, EHR glitches, guideline changes), because they believed it would help maintain the accuracy and credibility of final performance scores.

Response: We appreciate the commenter's support for our policy regarding the removal of measures from scoring when data are compromised by external errors, as this approach helps maintain the accuracy and credibility of final performance scores. The policy outlined at § 512.725(h)(4)(ii)(A) provides that for each measure impacted by significant changes or errors prior to the data submission deadline, performance is based on data for 9 consecutive months of the applicable ASM performance year. Significant changes or errors are defined as changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results, including but not limited to changes to codes, inadvertent omission of codes, or changes to clinical guidelines or measure specifications. This policy ensures that ASM participants are not unfairly penalized for circumstances beyond their control while maintaining robust quality measurement standards.

After consideration of public comments, we are finalizing our proposed provisions related to the removal, addition, and maintenance of technical specifications of quality measures as proposed at § 512.725(d).

(f) Maintenance of Technical Specifications for Quality Measures

We proposed at § 512.725(d) to communicate any updates or changes to the quality measure sets via notice and comment rulemaking. This would include releasing technical specifications for the required quality measures in a form and manner determined by CMS for each ASM performance year. We intend to use the most recent MIPS version of the technical specifications for all applicable measures. For non-MIPS measures, we would release the measure specifications in advance of the ASM performance year in which the specifications would be applicable via notice-and-comment rulemaking. If any changes are made to specifications for MIPS measures, and ASM chooses not to adopt these changes, we proposed releasing the measure technical specifications applicable to ASM via notice-and-comment rulemaking before the start of each ASM performance year.

We solicited comments on our proposal to use the most recent MIPS version of technical specifications of quality measures for each ASM performance year. We also sought comment on our intent to release the technical specifications of non-MIPS measures via notice-and-comment rulemaking, and if it allows adequate time for ASM participants to make any needed adjustments to data collections systems or practice workflows.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to maintain technical specifications for MIPS measures in ASM, because this is more cost-effective and efficient than developing and maintaining separate measures for ASM and MIPS. Commenters believed that any re-specification of existing MIPS measures would be appropriate for both MIPS and ASM. Additionally, a commenter recommended that CMS finalize and release all MIPS and non-MIPS measure specifications no later than 1 year prior to the start of the applicable ASM performance year.

Response: We appreciate the supportive feedback regarding our proposal to maintain technical specifications for MIPS measures in ASM, and we agree that this approach is more cost-effective and efficient than developing and maintaining separate measures for ASM and MIPS. We concur with commenters that maintaining consistent specifications reduces administrative burden for participants who may be reporting under multiple CMS quality programs and ensures alignment across our quality

measurement initiatives. We also agree that any re-specification of existing MIPS measures would be appropriate for both programs, promoting consistency and reducing confusion for participating clinicians. We will rely on the MIPS program to release technical specifications in accordance with their typical timeframes.

After consideration of public comments, we are finalizing our proposal to communicate any updates or changes to the quality measure sets, including the releasing of technical specifications for the required quality measures in a form and manner determined by CMS for each ASM performance year as proposed at § 512.725(d).

(g) Data Submission Criteria for the Quality ASM Performance Category

We proposed at § 512.725(e)(1) that ASM participants submitting data that are not administrative claims-based measures would be required to submit data for each measure using one of the measure's collection types identified for each required quality measure in the finalized measures in Table B-D4. We proposed at § 512.725(e)(2) that for the applicable ASM performance year, each ASM heart failure participant would report all of the measures in the heart failure quality measure set as described in section III.C.2.d.(2).(b) of this final rule and each ASM low back pain participant would report all the measures in the low back pain quality measure set as described in section III.C.2.d.(2).(c) of this final rule.

We solicited comments on the proposed form, manner, and timing of quality measures reporting at § 512.725(e).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported making quality measures available via the eCQMs for ASM quality measure set. A commenter believed that eCQMs help maximize the efficiency of electronic health systems while providing more accurate and comprehensive data. Another commenter supported the inclusion of eCQMs because they believed it aligns with other CMS programs, reduces reporting burden, and is a reliable and efficient method for data reporting. A few commenters recommended that all ASM measures have eCQM versions to make reporting more consistent and to support the transition towards digital quality measurement. A commenter recommended that CMS eliminate all measures that are not eCQMs in the ASM while another recommended that all measures be eCQMs or claims-based measures.

Response: We appreciate the support expressed by commenters for making quality measures available via eCQMs for the ASM quality measure set. We agree with commenters that eCQMs support the efficiency of electronic health systems while providing accurate and comprehensive data, and we recognize their value in aligning with other CMS programs to reduce reporting burden. We support the transition towards digital quality measurement and support making eCQM versions available for ASM measures where technically feasible and clinically appropriate. While we understand the recommendation to remove non-eCQM measures, we must balance this goal with the need to maintain clinically meaningful measures that may not yet have fully developed eCQM specifications. We will consider eCQM availability for ASM measures over time, supporting participants' preference for reliable and efficient electronic reporting methods.

Comment: A commenter requested clarification on what “using one” collection type means. Specifically, they sought clarity on whether an ASM participant who chooses to report using the eCQM collection type would still be required to report on the MIPS CQM, as that would constitute a different collection type.

Response: We appreciate the commenter’s question seeking clarification on what "using one" collection type means for ASM quality measure reporting. Each measure must be reported using one collection type per performance period. If a measure has both CQM and eCQM collection types available, the ASM participant can choose which collection type they prefer to use for that specific measure.

Participants do not need to report both collection types for the same measure; they should select the single collection type that works best for their practice's technical capabilities and reporting infrastructure. This approach provides flexibility while maintaining consistency in how each individual measure is reported within ASM.

Comment: Several commenters did not support limiting the collection type of measures in ASM and recommended that CMS maintain flexibility for ASM participants in collecting, validating, and reporting their quality measurement data. They believed that reporting flexibility ensures that clinicians can select the most practical submission pathway based on the capabilities available in their EHR environment while also minimizing administrative burden. Additionally, they believed that ASM participants will have to use multiple reporting methodologies to meet measure reporting requirements,

since some of the proposed measures can be reported either through MIPS CQMs or eCQMs. The commenters believed that some providers have limited technical infrastructure to successfully report eCQM and recommended that CMS allow ASM participants to select the collection type that is most appropriate with their existing reporting platforms when reporting measures.

Response: We appreciate commenters for their feedback. To clarify, ASM allows participants to choose a measure's collection type if more than one collection type is available. For example, if a measure is a CQM or an eCQM, the participant may choose to report the CQM or the eCQM, but not both. We promote the adoption and reporting of eCQMs; however, if a measure specification allows reporting via CQM, we will allow participants to report using that collection type.

After consideration of public comments, we are finalizing our proposed data submission requirements for the quality ASM performance category as proposed at § 512.725(e).

(h) Data Completeness Requirement and Case Minimums for the Quality ASM Performance Category

(i) Data Completeness Requirement

We proposed at § 512.725(f)(1) to set a data completeness requirement of at least 75 percent beginning in the 2027 ASM performance year. Data completeness is essential to ensure that data submitted on quality measures are sufficiently complete to accurately assess each ASM participant's quality performance. The data completeness requirement means that an ASM participant submitting measure data on MIPS clinical quality measures (MIPS CQMs) or eCQMs must submit data on at least a specific percent of their patients that meet the measure's denominator criteria, regardless of payer. Also, the inclusion of eCQMs in ASM measure sets more easily enables submission of data on 100 percent of the patient records in a provider's EHR, making data completeness more achievable. We believe it is important to maintain high data completeness to ensure the most accurate assessment of ASM participants. The CY 2025 PFS final rule set the CY 2025 MIPS performance period/2027 MIPS payment year MIPS data completeness requirement for the quality performance category at 75 percent (89 FR 98383 through 98387). Prior to this, the MIPS data completeness requirement had been periodically increasing from where it started, which was at least 50 percent to where it currently is (89 FR 98383 through 98387). We do not intend to continue to align with MIPS data completeness requirements and instead propose to assess changes to the ASM quality measure data completeness as

needed for model-specific purposes. Since some ASM participants would not have previously reported to MIPS and, therefore, may have limited experience and capabilities with quality reporting of this type, we considered data completeness requirement lower than 75 percent for 2027 ASM performance year and then increasing to 75 percent beginning in the 2028 ASM performance year 2028.

We also proposed at § 512.725(f)(2) that ASM participants would receive zero "measure achievement points," which we propose at § 512.705 to mean numerical values assigned to an ASM participant's reported performance data that we use to calculate an ASM performance category score, for any required measure that does not meet the proposed data completeness requirement. Meeting the data completeness requirement ensures that the measure represents an appropriate percentage of the clinical population applicable for a given quality measure. Therefore, we believe that not meeting the proposed data completeness requirement for a given required quality measure should result in the ASM participant receiving zero achievement points for that measure.

Finally, we proposed at § 512.725(f)(3) that we exclude from an ASM's participant total measure achievement points and total available measure achievement points any required measures meet the respective measure's data completeness requirement, but do not have a benchmark. As discussed later in this section of this final rule, we believe that it would not be appropriate to score quality measures for which we cannot determine a benchmark.

We sought comments on our proposed definition of "measure achievement points" proposed at § 512.705. We sought comments on the proposed data completeness requirement of 75 percent at § 512.725(f)(1) and whether a different data completeness percentage that we considered would be more appropriate. We also sought comment on our proposal at § 512.725(f)(2) that ASM participants would receive zero measure achievement points for any submitted quality measure that does not meet the data completeness requirement. Finally, we sought comment on our proposal at § 512.725(f)(3) for not scoring measures that meet data completeness requirements but for which we cannot determine a benchmark.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed data completeness requirement of 75 percent.

Response: We appreciate the commenter for supporting this requirement. We believe it is vital to the integrity of our quality measures that we set an adequate data completeness threshold.

Comment: A commenter expressed concern about enforcing a strict 75 percent data completeness threshold and believed that specialists who provide episodic care may be unable to fully document all required fields when reporting measures.

Response: We appreciate the concern regarding the 75 percent data completeness threshold and understand the documentation challenges specialists providing episodic care may face. However, we believe maintaining this threshold is essential to ensure the integrity and reliability of quality measurement under ASM. The 75 percent standard aligns with other CMS quality programs and represents the minimum level needed for statistically reliable and clinically meaningful quality scores. We encourage participants to work with their health IT vendors in advance of model start to optimize their documentation workflows. This period should provide adequate time to meet this important standard.

Comment: A few commenters did not support assigning zero measure achievement points for any submitted quality measure that does not meet the data completeness requirement. A commenter believed that because of the limited number of measures in the ASM, this may increase the number of lower scores. Another commenter recommended that CMS avoid point-based penalties for partial or incomplete reporting during the early implementation phases of the ASM. A commenter recommended that CMS create denominator exceptions when information is not accessible to an ASM participant so that incomplete records are not considered failures. Another commenter recommended that when certain measures are removed or suppressed due to data completeness requirements, such as the lack of a benchmark, CMS should automatically assign full points for the affected measure to prevent an unfair distribution of scores and mitigate the impact of smaller measure sets.

Response: We appreciate the feedback regarding our proposal to assign zero achievement points for quality measures that do not meet the data completeness requirement.

However, we will maintain the zero achievement points policy for quality measures that fail to meet data completeness requirement. We must be able to appropriately compare providers, and therefore, we believe there should be an incentive to report complete data. A single quality measure represents only a portion of the overall performance assessment approach in ASM, so if data completeness is not met for

one measure, there are several other compensating areas including the other quality measures, as well as the cost, improvement activities, and Promoting Interoperability performance categories. Quality measures have built-in denominator exclusions that ASM will adhere to for reliability purposes, and we will not impose additional exclusions beyond these established parameters. If we score measures that do not meet data completeness due to inadequate data capture by the participant, then participants may choose which portion of data to report and could be at an advantage in performance comparisons. Relaxing the data completeness requirement would undermine the integrity of the performance comparison approach. We believe promoting data completeness is essential to accurate assessment and the integrity of the model's goals and payment adjustment methodology. The limited number of measures in ASM makes each measure's data quality even more critical for meaningful performance evaluation, and maintaining this standard ensures that all participants are held to the same rigorous reporting requirements that support fair and accurate comparisons across the model.

Comment: A few commenters supported the alternative proposal to set the data completeness requirement to lower than 75 percent beginning in the 2027 ASM performance year and then implementing a phase-in approach over the first few years of the model performance period to gradually increase the data completeness requirement. They believed it would provide ASM participants with time to adjust to the new model, minimize burden, and reduce inequity. A commenter recommended that CMS provide a clear guide and consider hardship exemptions when setting the data completeness threshold.

Response: We appreciate the feedback from commenters supporting a phased-in approach to the data completeness requirement, and we understand the concerns about providing ASM participants with adequate time to adjust to the new model while minimizing burden and reducing potential inequities. However, after careful consideration of all comments received, we have decided to maintain the 75 percent data completeness requirement beginning with the 2027 ASM performance year. We believe this threshold is essential to ensure the integrity and reliability of quality measurement in ASM and represents the minimum level of data completeness necessary to generate statistically reliable quality scores. The 75 percent standard aligns with established requirements in other CMS quality programs and reflects our commitment to maintaining robust quality measurement that can accurately assess performance and support valid comparisons across ASM participants. We believe that the notice provided by this rule and

our planned release of a preliminary eligibility list in early CY 2026 will provide adequate time for participants to work with their health IT vendors and optimize their documentation workflows to meet this standard.

Comment: A commenter recommended that CMS waive or lower the 75 percent data completeness threshold for PRO-PMs for at least the first performance year. They also suggested that CMS consider omitting or reducing the weight of PRO-PMs in determining payment adjustments. The commenter further recommended that CMS incorporate a voluntary "rapid learning collaborative program" in which participants agree to use a learning platform for collection and analysis of patient-reported data.

Response: We appreciate the commenter's feedback regarding PRO-PM data completeness requirements and payment adjustment considerations. However, we will not be changing the 75 percent data completeness threshold for PRO-PMs, as this standard is essential to ensure the integrity and reliability of patient-reported outcome measurement under ASM. We will not be removing or reducing the weight of PRO-PMs in determining payment adjustments, as these measures are a vital aspect of our quality measurement strategy and represent critical patient-centered outcomes fundamental to assessing care quality and effectiveness. We appreciate the recommendation for a voluntary "rapid learning collaborative program" and intend to pursue efforts to promote learning and diffusion among ASM participants regarding best practices for quality measurement and beyond.

We did not receive specific comments on our proposed definition of "measure achievement points," so we are finalizing it as proposed at § 512.705.

After consideration of public comments, we are finalizing the proposal to set the data completeness threshold at least 75 percent as proposed at § 512.725(f)(1). We are finalizing the proposal that participants receive zero measure achievement points for any submitted quality measure that does not meet the data completeness requirement as proposed at § 512.725(f)(2).

Finally, as we did not receive any comments on the proposal, we are finalizing the proposal that we would exclude quality measures that do not have a benchmark in the calculation of the quality ASM performance category score as proposed at § 512.725(f)(3).

(ii) Minimum Case Requirements

We seek to ensure that ASM participants are measured reliably, therefore, we proposed at § 512.725(g)(1) to use 20 cases as the minimum case requirement for each quality measure. We proposed at § 512.725(g)(2) that ASM participants that report measures with fewer cases than the case minimum for the measure and meet the data completeness requirement proposed at § 512.725(f)(1) would receive recognition for submitting the measure, but we would not include the measure in the quality ASM performance category scoring as described later in this section of this final rule. We believe this case minimum is appropriate as it aligns with the case minimum under MIPS as defined at § 414.1380(b)(1)(iii).

We solicited comments on our proposed case minimum for quality measures at § 512.725(g). We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support setting the case minimum requirement to 20 cases for each quality measure because they believed it is statistically insufficient. A commenter believed that this case minimum systematically excludes rural providers. Another commenter believed that the 20-case minimum may be insufficient to generate stable benchmarks for certain measures and recommended CMS to evaluate safeguards or confidence intervals for measures that may demonstrate year-to-year variation. A commenter recommended that CMS adopt a higher minimum because it would also reduce the risk of punishing providers who treat more vulnerable patients.

Response: We acknowledge the concerns raised about statistical sufficiency, rural provider inclusion, and benchmark stability. For each measure, the case minimum was established during the measure development process and determined to be reliable and valid at this case minimum threshold, based on established standards and statistical analysis conducted during measure testing and validation. We believe most ASM participants should meet this minimum considering that the threshold for inclusion in the model requires meeting the 20 EBCM cost measure minimum, meaning they see at least 20 patients with the relevant condition, and likely many more given the nature of specialty practice patterns. Therefore, these clinically specific quality measures should be applicable to ASM participants, and the case minimum should be achievable for most participants who treat sufficient volumes of patients with

these conditions. Also, we are finalizing allowing for flexibility for small practices to report quality measures in the quality ASM performance category at the TIN-level, as further described in section III.C.2.d.(1).(b) in this final rule. However, we do not plan to increase the minimum case requirement, as the current threshold aligns with other thresholds established throughout the model, is consistent with existing measurement specifications and criteria used in other CMS quality programs and avoids excluding providers who should appropriately be assessed under the model. Regarding concerns about year-to-year variation and benchmark stability, we will monitor measure performance data and evaluate the need for additional safeguards or statistical adjustments as we gain experience with the model. Our goal is to balance statistical reliability with inclusive participation that captures the spectrum of providers delivering care to Medicare beneficiaries with these conditions, while ensuring that quality measurement remains meaningful and actionable for driving improvements in patient outcomes.

Comment: A commenter supported the proposal to exclude measures from the quality ASM performance category score if the case minimum is not met. The commenter also recommended that clinicians should not be required to participate in the ASM for a reporting year in which they do not meet the case minimums.

Response: We appreciate the commenter's support on case minimums and the proposal to exclude measures from the quality ASM performance category score when the case minimum is not met. We agree that this approach ensures statistical reliability and meaningful quality measurement for ASM participants. However, we will not exclude providers from participating in ASM for a reporting year in which they do not meet the case minimums for specific quality measures. Instead, those measures where providers do not meet the minimum case requirements will not be counted against them in their overall performance assessment, allowing them to continue participating in the model while ensuring fair and statistically valid quality measurement.

After consideration of public comments, we are finalizing our proposed provision for minimum case requirements for quality measures as proposed at § 512.725(g).

(i) Quality Measure Achievement Points and Quality ASM Performance Category Scoring

(i) Quality Measure Achievement Points

We proposed at 512.725(h)(1)(i) to assign 1 to 10 measure achievement points to each measure based on how an ASM participant performance compares to measure-specific benchmarks determined as described in section III.C.2.d.(2).(i) of this final rule. We proposed at § 512.725(h)(1)(iii) that if an ASM participant fails to submit a measure required under the quality ASM performance category, then the ASM participant would receive zero measure achievement points for that measure. We proposed at § 512.725(h)(1)(ii) and (iii) that measures reported by ASM participants must have the required case minimum as applicable for each measure, as proposed at § 512.725(g)(1), and meet the data completeness requirement, as proposed at § 512.725(f)(1), to receive a score. For example, if an ASM participant reports a measure that meets the data completeness requirement rule but does not meet the required case minimum, then the ASM participant would not be scored on that measure, and that measure score would not be factored into the ASM participant's quality ASM performance category score. An ASM participant who reports a measure that does not meet the data completeness requirement but meets the required case minimum of this proposed rule would receive a score of zero for the measure. An ASM participant who does not report the measure would receive a score of zero for the measure. We proposed at § 512.725(h)(1)(iv) that an ASM participant that submits data for the same measure under two different collection types, if applicable, would be scored on the data submission that leads to the greatest number of achievement points for that required measure.

The quality ASM performance category score would be the sum of all the measure achievement points assigned for the scored measures required for the quality ASM performance category divided by the sum of total possible measure achievement points.

We also proposed not to score measures for which we could not determine a benchmark for a given ASM performance year as described in section.III.C.2.d.(2)(i)(ii) of this final rule. In this situation, the quality ASM performance category score would not include any measure or measures for which a benchmark could not be determined. We believe that it would be unfair to penalize ASM participants due to a lack of a benchmark.

We sought comments on this proposed quality ASM performance category scoring approach to assigning measure achievement points as described at § 512.725(h)(1).

We did not receive specific comments on this provision, and therefore, we are finalizing our proposed provisions for quality ASM performance category scoring as proposed at § 512.725(h)(1).

(ii) Benchmarking

For the quality ASM performance category, we proposed at § 512.725(h)(2) that the ASM performance standard is a measure-specific benchmark. We proposed at §§ 512.725(h)(2)(i)(A) through (C) to determine benchmarks for each quality measure and for each of the measure's collection types using data reported by ASM participants, to the extent feasible, during the ASM performance year, from a previous ASM performance year, or from another period determined by CMS. The benchmark determination is contingent on relevant available data for accurate calculation that is specific to ASM participants. For measures with an administrative claims-based collection type, we proposed at § 512.725(h)(2)(iii) to calculate the benchmark using performance on the measure during the current ASM performance year. We believe it is important to determine separate benchmarks for each of a measure's collection types since performance varies by collection type in MIPS.[249] We considered determining one benchmark per quality measure regardless of collection type since having a single benchmark may help ASM participants more readily calibrate their performance. Given the differences in MIPS performance by collection type for measures that we proposed to require in ASM,[250] we believe it would be more appropriate to calculate a benchmark for each collection type.

We proposed at § 512.725(h)(2)(iv) to determine benchmarks for each measure's collection type using deciles based on the applicable period of data we use to determine the measure's benchmark. Then, we would evaluate an ASM participant's actual measure performance during the ASM performance year to determine the number of measure achievement points that should be assigned based on where the actual measure performance falls within the benchmark. We proposed establishing benchmarks using a percentile distribution, separated by decile categories, because it translates measure-specific score distributions into a uniform distribution of ASM participants based on actual performance values. For

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[249] https://qpp.cms.gov/resources/performance-data.
[250] https://qpp.cms.gov/resources/performance-data.

each set of benchmarks, we proposed to calculate the decile breaks for measure performance and assign measure achievement points for a measure based on which benchmark decile range the ASM participant's performance rate on the measure falls between. For example, an ASM participant in the top decile would receive 10 measure achievement points for the measure, and an ASM participant in the next lower decile would receive measure achievement points ranging from 9 to 9.9. We proposed to assign partial measure achievement points to prevent performance cliffs for ASM participants near the decile breaks. The partial measure achievement points would be assigned based on the percentile distribution

We proposed at §§ 512.725(h)(2)(ii)(A) through (C) that we only calculate benchmarks for measures that have a minimum of 20 ASM participants that report the measure: (1) meeting the data completeness requirement as proposed at §§ 512.725(f)(1) through (2) meeting the required case as proposed at §§ 512.725(g)(1) and (3) a performance rate greater than zero. We proposed a minimum of 20 because our benchmarking methodology relies on assigning measure achievement points based on decile distributions with decimals. A decile distribution requires at least 10 observations. We would double the requirement to 20 so that we would be able to assign decimal measure achievement point values and minimize cliffs between deciles. Given the mandatory participation of ASM and the mandatory quality measure sets, we do not anticipate that we would encounter challenges with meeting this proposed minimum of 20 ASM participants reporting a measure to determine a benchmark.

We solicited comments on our proposed benchmark determination process as proposed at § 512.725(h)(2) and all alternatives considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support calculating benchmarks for each quality measure and collection type because they believed it may unintentionally penalize clinicians who adopt certain reporting pathways that perform differently due to measure specifications or data completeness.

Response: We appreciate the feedback regarding our proposal to calculate benchmarks for each quality measure and collection type. However, we are not concerned about the potential for unintentionally penalizing clinicians who adopt certain reporting pathways, as we believe our benchmarking methodology appropriately accounts for differences in measure specifications and data

completeness across collection types.

Our approach to calculating separate benchmarks by collection type is designed to ensure fair and accurate comparisons among participants using the same reporting method, thereby maintaining the integrity of performance assessment while providing flexibility in reporting options. This methodology aligns with established practices in other CMS quality programs and supports equitable evaluation of clinical performance regardless of the chosen collection pathway.

Comment: A commenter recommended that CMS compare the calculated ASM benchmarks to the corresponding MIPS benchmarks by collection type and select the benchmark that is most favorable to the ASM participant because they believed it would ensure fair and equitable scoring.

Response: We appreciate the commenter's recommendation regarding benchmark comparison between ASM and MIPS programs. However, we will not be comparing the calculated ASM benchmarks to the corresponding MIPS benchmarks by collection type and selecting the benchmark that is most favorable to the ASM participant. ASM has different goals than MIPS and adopting this approach could undermine how ASM will make more like-to-like performance comparisons to achieve in improved care delivery. ASM is specifically designed to test innovative payment and care delivery approaches for specialty care, with benchmarks that reflect the unique patient populations, care patterns, and quality improvement objectives of the participating specialties. The ASM benchmarks will reflect performance from clinicians in each ASM cohort, whereas MIPS benchmarks would not reflect the performance of our participants and would introduce heterogeneity in the form of different provider types. Using MIPS benchmarks could undermine the model's ability to drive meaningful change and improvement in specialty care settings, as it would dilute the incentives for participants to achieve the higher performance standards that ASM is designed to promote. Our ASM-specific benchmarks are calibrated to support the model's goals of improving patient outcomes and reducing costs within the specialty care context.

Comment: A commenter recommended that CMS be transparent about the benchmarks it uses.

Response: We appreciate the commenter's recommendation for transparency regarding the benchmarks we use in ASM. We believe our proposed approach provides substantial transparency through the detailed methodology outlined in our regulations.

Our benchmarking process will determine measure-specific benchmarks for each quality measure and

collection type using data from ASM participants during the performance year or previous periods, with separate benchmarks calculated for each collection type due to performance variations observed in MIPS. The benchmark methodology uses decile distributions based on actual ASM participant performance, with measure achievement points assigned based on where a participant's performance falls within these deciles. We will only calculate benchmarks for measures that have a minimum of twenty ASM participants reporting the measure while meeting data completeness and case minimum requirements. This approach ensures statistical reliability while providing clear, performance-based standards that all ASM participants can understand and work toward achieving. We plan to release the benchmarks in a form and manner determined by CMS for each performance year.

Comment: A few commenters did not support the proposed quality benchmarks requirements and believed that if developed without specialty input, it would risk misaligning incentives by undervaluing the clinical complexity and safety requirements of image-guided spinal interventions performed in the office setting. A commenter believed that benchmarks should account for the precision, specialized equipment, and significant physician expertise that interventional pain procedures require. They were concerned that if benchmarks do not account for these factors, then the benchmarks could distort clinical decision-making and diminish access to these appropriate services.

Response: We appreciate the feedback regarding quality benchmark requirements and understand the concerns about specialty input and the unique aspects of interventional pain procedures. However, we believe our proposed benchmarking methodology appropriately addresses these concerns by using data reported specifically by ASM participants rather than external standards that may not reflect specialty practice patterns. Our approach to determining benchmarks for each quality measure using data from ASM participants during the performance year or previous ASM performance years ensures that benchmarks are based on actual performance within the specialty care context. The methodology accounts for the clinical complexity and specialized nature of interventional procedures by establishing benchmarks using decile distributions based on actual ASM participant performance. The participants included in each cohort supports more like-to-like comparisons, addressing concerns of broad differences in care patterns between providers treating different conditions.

By calculating benchmarks for each measure's collection types using ASM participant data, we

ensure that the unique characteristics of specialty care, including the precision, specialized equipment, and physician expertise required for interventional pain procedures, are inherently reflected in the performance standards. This participant-specific benchmarking approach prevents the misalignment of incentives that commenters were concerned about, as the benchmarks will be calibrated to the actual performance patterns of ASM participants in a specialty care setting.

Comment: A few commenters did not support using deciles for benchmarks because they believed that scoring clinicians according to a distribution and subjecting those in the bottom deciles to the maximum risk could harm high-performing providers and those who are improving year-over-year but in the lower decile. They believed that not recognizing both attainment and improvement creates a negative behavioral economic incentive, where clinicians who are improving but still ranked low may feel discouraged to improve further. A few commenters requested clarity on the standard for what constitutes a "good" quality measure score. These commenters recommended that CMS establish external benchmarks that define acceptable performance for quality measures and believed this approach would reduce reliance on relative scoring and avoid unfair penalties.

Response: We appreciate the feedback regarding our use of deciles for benchmarking in ASM and understand the concerns about potential negative impacts on high-performing providers and those showing improvement. However, we believe that creating a benchmark based on data reported by a group of similar providers provides meaningful quality assessment and accountability within the specialty care context. Our decile-based approach is designed to incentivize value and reward clinicians who are delivering high-quality care while encouraging those who are performing below their peers to improve their practices. This relative scoring methodology ensures that we maintain appropriate performance standards that evolve with the overall performance of the ASM participant pool, rather than static benchmarks that may become outdated or inappropriate over time. Regarding the request for external benchmarks that define "acceptable" performance, we believe that specialty care quality is best evaluated in the context of peer performance rather than external standards that may not reflect the realities of specialty practice patterns or patient populations. The decile approach ensures that quality expectations remain appropriately challenging and relevant to the specific clinical contexts within ASM. We will continue to review our benchmarking approach as the model evolves to ensure it effectively rewards high-

quality care delivery and promotes continuous improvement while maintaining fair and meaningful performance standards. Our goal is to create a system that recognizes excellence, supports improvement, and ultimately benefits Medicare beneficiaries through enhanced quality of specialty care.

After consideration of public comments, we are finalizing our proposed provisions for quality measure benchmarking as proposed at § 512.725(h)(2).

(iii) Topped-out Quality Measures

We proposed at § 512.725(h)(3) that we would identify topped out measures in the benchmarks for each ASM performance year, based on within-model performance on each measure. We considered but are not proposing an initial policy regarding topped out measures and differential benchmarking for measures with a topped-out status. MIPS defines at § 414.1305 a topped out non-process measure as a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors; MIPS also defines at § 414.1305 a topped -out process measure as measure with a median performance rate of 95 percent or higher. We proposed monitoring during the initial ASM performance year(s) before designating an ASM measure with topped out status. We proposed using a definition like the definition used by MIPS and the Hospital Value-Based Purchasing (HVBP) Program: a Truncated Coefficient of Variation less than 0.10 and the 75th and 90th percentiles are within 2 standard errors as defined at § 412.164(c)(3) (88 FR 59333); or median value for a process measure that is 95 percent or greater (80 FR 49550). Topped out measures are of concern as it makes it difficult to assess relative performance to most accurately score the quality ASM performance category. However, since all ASM participants reporting one of the two measure sets would only be compared among others also reporting that measure set, and all the measures are mandatory to report, the benefit of selecting a topped-out measure is nullified. In this way, the reasoning for removing topped out measures is also nullified. Several of the measures included in our measure sets are topped out in other programs, such as MIPS, potentially because MIPS participants can select the measures on which they believe they would perform well. It is unclear whether requiring ASM participants to report a measure that is topped out in MIPS would present the same issues typically associated with topped-out measures or if the appearance of being topped out is simply due to voluntary reporting by only the highest performers in MIPS.

We solicited comment on our proposal at § 512.725(h)(3) to identify topped out measures in the benchmarks for each ASM performance year, based on within-model performance on each measure, as well as all alternatives considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters generally supported not removing topped out measures in ASM. A commenter encouraged CMS to include topped out measures, because they represent established standards of high-quality care and that maintaining these measures helps ensure ongoing focus on critical aspects of care and consistency across the model. Another commenter recommended that CMS consider mitigation strategies for topped out measures, such as narrowing measure definitions, transitioning to outcome-focused specifications, or suppressing topped out measures from final scoring to avoid clustering.

Response: We appreciate the supportive feedback from commenters regarding our approach to topped out measures in ASM.

We will continue to identify topped out measures within ASM but plan to not immediately remove them from the measure set. Instead, we will carefully evaluate each topped out measure's continued relevance and consider the mitigation strategies suggested by commenters to address performance clustering while maintaining the clinical integrity these measures provide. Any changes to our approach for handling topped out measures will be addressed through notice-and-comment rulemaking, ensuring appropriate interested parties' engagement and transparency in our decision-making.

Comment: A few commenters generally did not support keeping topped out measures in ASM and recommended CMS replace topped out measures with metrics that meaningfully differentiate performance and reward improvement. These commenters also recommended that CMS incorporate external benchmarks and set a "floor" for negative adjustments once providers achieve collective improvement on a topped out measure.

Response: We appreciate the feedback regarding topped out measures in ASM and understand the desire for metrics that better differentiate performance. However, we believe fewer measures would be

considered topped-out in ASM given the mandatory reporting of all quality measures applicable for each ASM cohort. Maintaining consistency during the model performance period allows participants to focus their quality improvement efforts effectively. We also do not intend to review external benchmarks or set a floor for negative adjustments as it would not align with ASM's performance assessment approach and goals. We will continue reviewing topped-out measures as the model progresses and assess their ability to meaningfully differentiate performance among ASM participants. While changes are unlikely, any modifications would be proposed through future notice-and-comment rulemaking to ensure appropriate interested parties engagement and transparency.

After consideration of public comments, we are finalizing the proposed topped-out measure policy as proposed at§ 512.725(h)(3).

(iv) Calculation of the Quality ASM Performance Score

We proposed at § 512.725(h)(4) to sum all quality measure achievement points determined for all measure reported by an ASM participant for an applicable ASM performance year. We would then divide the total achievement points by the total available measure achievement points for measures reported by the ASM participant that meets the case minimum requirements as defined at § 512.725(g) to determine an overall quality ASM performance category score, which could not exceed 100 percentage points.

We proposed at § 512.725(h)(4)(ii) that if data used to calculate a score for a quality measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the quality measure score would lead to misleading or inaccurate results, then the affected quality measure would be based on data for 9 consecutive months of the applicable ASM performance year. We proposed at § 512.725(h)(4)(ii)(A) to consider "significant changes or errors" regarding instances in which a quality measure score could not be calculated as changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We further proposed at § 512.725(h)(4)(ii)(A) that significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. We also proposed at § 512.725(h)(4)(ii)(B) that we would publish a list of all measures scored in a form and manner specified by CMS. Finally, we proposed at § 512.725(h)(4)(ii)(C) that if CMS determines

sufficient measure data is not available, or that there is the possibility of patient harm or misleading results, a measure would be excluded from a participants score. We believe these proposed policies would appropriately adapt the proposed quality ASM performance category scoring policies so that ASM participants would not be penalized for changes or errors in the measure and associated submitted data that would be outside the control of the ASM participant.

We proposed at § 512.735(h)(4)(iii) that an ASM participant would not receive a quality ASM performance category score if the ASM participant meets the quality ASM performance category data submission requirements proposed at § 512.720(a)(1)(i) but does not meet the case minimum requirements for any of the required quality measures in their applicable quality measure set. As discussed in sections III.C.2.e.(2)(b) and III.C.2.f.(4) of this final rule, the ASM participant in this situation would not receive a payment adjustment for the applicable ASM payment year. We believe that we should hold all ASM participants accountable to performance on quality. Accordingly, it would be inappropriate to evaluate the performance of an ASM participant that reports complete quality measure data but cannot meet the case minimums for any required measure within the applicable quality measure set since they would not have sufficient case volume by which to evaluate clinical quality.

We solicited comments on our proposed approach to calculate measure achievement points for each required quality measure and determine benchmarks for quality measures in the quality ASM performance category. We also solicited comments on our proposed approach to monitor for topped out measure status and future considerations for how we should approach and manage identified topped out measures in ASM. Finally, we sought comment on our proposal to calculate the quality ASM performance category score, as well as the proposed exceptions that could prevent the calculation of an individual quality measure score. or an overall performance category score.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support the proposed quality performance category scoring methodology because they believed the proposed scoring methodology is different than MIPS and that ASM effectively creates two separate sets of scores for one specialty group. The commenter believed that since ASM does not provide specific benchmarks for when a positive or negative payment adjustment

may be applied, clinicians and their group would have no actionable information or incentive to improve their performance. The commenter expressed concern that the specialty group would also have to identify where to place its limited resources to improve performance, deciding whether to focus on the 6 measures required to report for MIPS or the measures that are required to report for the individuals required to participate in the ASM.

Response: We appreciate the feedback regarding our proposed quality performance category scoring methodology for ASM. ASM is intentionally designed as a distinct alternative payment model with its own performance standards and benchmarks, separate from MIPS, to test innovative approaches to specialty care delivery and payment focused on high cost, highly prevalent chronic conditions. While we understand the concern about managing multiple reporting requirements, ASM's focused measure set is specifically tailored to the clinical conditions and care patterns relevant to the participating specialties and targeted chronic conditions, which differs from the broader scope of MIPS measures. We also have used MIPS measures in our measure set to reduce burden and align with other CMS programs. Regarding benchmarks and payment adjustments, our methodology provides clear performance standards through decile-based scoring that allows participants to understand their relative performance and identify areas for improvement. The model's design ensures that participants have actionable information through transparent scoring methodologies and performance feedback, even though the payment adjustment methodology may differ from other CMS programs.

Comment: A commenter wanted clarification on how quality measures are counted and scored for clinicians. They requested whether clinical action, such as a screening performed by one provider within a TIN (regardless of ASM eligibility), could be "counted" by an ASM participant to meet their own quality measure requirements. The commenter recommended that clinical actions by any provider within the same TIN should count toward meeting quality measures, as the patient’s care is managed within the same TIN.

Response: We appreciate the commenter’s question seeking clarification on how quality measures are counted and scored for clinicians in ASM. To understand each individual measure's specific requirements, we refer readers to the measure specifications which are publicly available and provide detailed guidance on measure calculation and attribution. In instances like the BMI screening and follow-

up measure, the measure looks to see if a BMI screening has occurred during the performance year and is documented in the patient's chart. In this instance, it can be conducted by someone else in the practice and the ASM participant can receive credit, assuming other measure criteria are met, and the screening is properly documented and attributed. ASM promotes individual accountability as quality and cost elements are scored at the TIN/NPI level. We recognize the collaborative nature of practice-level efforts, and practice-level efforts may be reflected in quality measure reporting as described by each measure's specifications. However, acknowledging the burden this may present to small practices, we are finalizing allowing for flexibility for small practices to report quality measures in the quality ASM performance category at the TIN-level, as further described in section III.C.2.d.(1).(b) in this final rule.

Comment: A few commenters did not support calculating a quality measure score based on nine consecutive months of data from the performance year in the event of significant changes or errors. A commenter shared their belief that shortening reporting periods is not feasible for eCQMs. Another commenter believed that partial-year scoring introduces inconsistency and distorts results. The commenters recommended that CMS suppress or remove the measure from scoring, which they believe is consistent with MIPS, rather than truncating the reporting period.

Response: We appreciate the feedback regarding our proposed approach to calculating quality measure scores when significant changes or errors occur during the performance year. We align with MIPS on the principle of protecting participants from circumstances beyond their control that could unfairly impact their quality scores. We did not propose a provision that would allow us to remove a measure from scoring when appropriate circumstances warrant such action. We understand the concerns raised about the feasibility of shortened reporting periods for eCQMs and the potential for partial-year scoring to introduce inconsistency in results. We will consider which of these two approaches, using 9 consecutive months of data or removing the measure from scoring entirely, would be most beneficial to participants in each specific situation and execute the approach that best serves the integrity of the measurement system and fairness to ASM participants. We will also review the MIPS approach to not truncate qualifying eCQMs as discussed in the CY 2024 PFS final rule (88 FR 79369) to determine if such an approach would be appropriate for ASM. Our decision-making process will consider the nature of the significant change or error, the impact on data quality and reliability, and the operational feasibility

for participants.

Comment: A commenter did not support suppressing measures when certified health IT is unavailable or when scoring could be misleading, because they believed this conflicts with CMS principles and ASM's regulatory structure. The commenter believed that proprietary PRO-PMs and undisclosed risk adjustment can create risks when health IT is unavailable.

Response: We appreciate the commenters feedback regarding our proposal. However, we believe this approach is fundamental to fair and accurate performance assessment. We have clarified that there are resources available to help participants understand PRO-PMs, including publicly available measure specifications and we believe these patient-reported outcome measures are vital tools for our assessment of care quality and patient-centered outcomes. We are aligning our approach with MIPS standards and methodology, which provides consistency across CMS quality programs and reduces administrative burden for participants who may be reporting under multiple programs. We believe that the measures in our proposed set represent the best available tools for assessing quality in our specialty care settings of focus, and therefore we will maintain the measure set as proposed.

After consideration of public comments, we are finalizing the proposed calculation of the quality ASM performance score as proposed at § 512.725(h)(4).

(3) Cost ASM Performance Category

The cost ASM performance category supports the model goals to improve quality care as measured through a focused measure set relevant to ASM's clinical specialties and targeted chronic conditions, while decreasing the cost of care for beneficiaries with ASM's targeted chronic conditions. The cost ASM performance category ensures that Medicare beneficiaries are receiving clinically appropriate, comprehensive, high-value care. The importance of the cost ASM performance category is reflected in the weight of the performance category contribution to the final score, discussed at section III.C.2.e.(1) of this final rule.

(a) Background

The cost ASM performance category is one of four ASM performance categories measuring an ASM participant's performance on the care delivered related to ASM's targeted chronic conditions. The cost ASM performance category incentivizes ASM participants to ensure Medicare beneficiaries are

receiving clinically appropriate, comprehensive, high-value care. Like the cost performance category under the MVPs, ASM participants in each ASM cohort would be scored on a condition-relevant EBCM. We proposed at § 512.730(b) to use two EBCMs specified for the MIPS cost performance category, the heart failure EBCM and the low back Pain EBCM. As discussed in this section, while we proposed to evaluate ASM participants on their performance on these 2 MIPS cost measures, and proposed to use the same MIPS cost benchmarking and scoring methodology finalized for the 2024 MIPS performance period defined at § 414.1380(b)(2)(i)(B), we proposed to use different benchmark ranges.

(b) Performance Year for Cost ASM Performance Category

Beginning with ASM payment year 2029, we proposed at § 512.730(a) that the ASM performance year for cost measures would be the full calendar year from January 1 to December 31 that occurred 2 years prior to an applicable ASM payment year. We believe that setting the ASM performance year for cost measures in this way aligns with MIPS as defined at § 414.1320 and would be easily adoptable by ASM participants.

We solicited comments on our proposed approach at § 512.730(a) for setting the ASM performance year for cost measures.

We did not receive public comments on the proposed performance year for cost measures, and therefore, we are finalizing this proposal as proposed at § 512.730(a).

(c) Cost Measure for the ASM Heart Failure Cohort

For the ASM heart failure cohort, we proposed at § 512.730(b)(1) to utilize the heart failure EBCM, a MIPS cost measure specified by CMS through rulemaking, to determine an ASM heart failure participant's cost ASM performance category score.[251] We proposed the heart failure EBCM, in part, because the Advancing Care for Heart Disease MVP (88 FR 80022 through 80025; 89 FR 99015 through 99019) includes it as one of the mandatory cost measures. The heart failure EBCM evaluates a participant's risk adjusted and specialty-adjusted cost to Medicare for beneficiaries receiving medical care to manage and treat heart failure.[252] We proposed the heart failure EBCM because the measure quantifies the costs of services that are clinically related to the participant's role in managing

[251] https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.
[252] https://www.cms.gov/files/zip/2024-cost-measure-information-forms-zip.zip-0.

care during a heart failure episode. We believe that the heart failure EBCM captures a targeted high-cost patient population, has robust clinician coverage, and can help lower Medicare spending. The heart failure EBCM is a complex, yet feasible, chronic condition measure that addresses care delivered to manage heart failure. We believe holding ASM heart failure participants accountable on the heart failure EBCM represents an opportunity to measure reductions in the cost of care for beneficiaries with heart failure.

Additionally, we proposed this measure and the focus on heart failure, generally, due to the prevalence of heart failure in the Medicare FFS population, and the high costs associated with the management of the disease and its complications. The incidence of heart failure increases with age, rising from 20 per 1,000 individuals aged 65 to 69 to more than 80 per 1,000 individuals over 80 years of age.[253] With an estimated 1 in 5 Americans 40 years and older expected to develop heart failure and 1 in 5 Americans expected to be 65 years or older by 2050, the number of Americans with heart failure is predicted to significantly increase in the future.[254] Further, heart failure was listed as the cause of death on 13.4 percent of all death certificates in the United States in 2018.[255] In addition to its prevalence, heart failure is also costly for the health care system. According to the Centers for Disease Control and Prevention (CDC), heart failure costs the United States $30.7 billion annually, including health care services, medications used to treat heart failure, and lost productivity.[256] A large contributor to heart failure-related health care costs may be inpatient admissions, with one study estimating that roughly 1 in 6 beneficiaries returned to the hospital for admission for heart failure-related reasons within 90 days of their initial discharge.[257]

We solicited comments on the proposed use of the heart failure EBCM at § 512.730(b)(1) to score the cost ASM performance category for the ASM heart failure cohort.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed concern with the proposal to use only administrative claims measures for the cost ASM performance category. The commenter recommended that CMS collaborate

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[253] Yancy et al. "2013 ACCF/AHA Heart Failure Guidelines." (2013). https://www.ahajournals.org/doi/pdf/10.1161/CIR.0b013e31829e8776.
[254] Yancy et al. "2013 ACCF/AHA Heart Failure Guidelines." (2013). https://www.ahajournals.org/doi/pdf/10.1161/CIR.0b013e31829e8776.
[255] Centers for Disease Control and Prevention (CDC) "Heart Failure." September 2020. https://www.cdc.gov/heartdisease/heart_failure.htm.
[256] Centers for Disease Control and Prevention (CDC) "Heart Failure." September 2020. https://www.cdc.gov/heartdisease/heart_failure.htm.
[257] Kilgore et al., "Economic burden of hospitalizations of Medicare beneficiaries with heart failure," Risk Management and Healthcare Policy 10 (2017): 63-70, doi: 10.2147/RMHP.S130341.

with patient groups and specialty societies to explore the use of alternative data sources, such as clinical registries. The commenter shared their belief that incorporating additional data sources could help ensure that ASM cost measures provide a more comprehensive and accurate assessment of patient care, including outcomes and preferences.

Response: We appreciate the commenter for sharing their concern regarding the cost ASM performance categories use of only administrative claims-based EBCMs. While clinical registries and patient-reported outcomes can be valuable for research and targeted quality improvement, we do not believe that they are appropriate for use in ASM because not all specialists have robust and mature registries whereas all ASM participants would generate claims used in EBCMs. Accordingly, we believe it crucial for all ASM participants within an ASM cohort to be scored on the same EBCM.

Comment: A few commenters offered general feedback related to EBCM measurement. A commenter suggested limiting eligibility to potential ASM participants that have a comparatively higher cost point until quality is measured so that there can be a low-cost, high-quality standard. Another commenter recommended that EBCM measurement volume should be robust to consider both major and minor complications and systematically prevent patient harm and unnecessary costs.

Response: We appreciate the commenters for their feedback related to EBCM measurement. We believe that ASM's approach to quality and cost measurement provides a more comprehensive approach to incentivizing quality improvements and reductions in unnecessary or low-value care spending related to ASM's targeted chronic conditions. We believe that a more complex participant identification logic comparing historical cost relative to some quality threshold would limit the potential impact of ASM by focusing on a narrow subset of specialists. By way of their construction, EBCM episodes account for attributable cost related to major or minor complications, which creates an incentive for the attributed clinician to improve upstream chronic condition management since they will perform better on the measure if they reduce unnecessary costs. For reasons discussed throughout this section of this final rule, we believe that the 20-episode threshold as part of the ASM participant eligibility criteria and as part of the cost ASM performance category measurement approach would be robust to evaluate clinicians on their efforts to reduce unnecessary costs while improving the quality of care.

Comment: A few commenters stated that retrospective EBCM attribution methodology prevents ASM participants from knowing their at-risk population prospectively. A commenter also shared their belief that episodes based on visits do not attribute all beneficiaries and leaves a measurement gap.

Response: We note that we only plan to use historical EBCM data to evaluate clinicians in mandatory geographic areas for the ASM participant eligibility criteria. ASM participants will be scored on the applicable EBCM as part of the cost ASM performance category that aligns with a given ASM performance year (that is, ASM participants for the 2027 ASM performance year will be scored using 2027 EBCM scores). While we expect that ASM participants would continue to reach the EBCM episode minimum of 20 to be scored, ASM participants that cannot be scored would not receive a final score or payment adjustment as described in sections III.C.2.e.(2).(b) and III.C.2.f.(4) of this final rule. We refer readers to our discussion of the EBCM attribution methodology earlier in this section of this final rule. However, prospective attribution of beneficiaries is not required for ASM's performance measurement framework. Should a participant want to identify beneficiaries that would likely trigger an episode, we believe they could do so by using the triggering and confirming codes provided in each EBCM's specifications. Further, we do not agree that use of EBCMs leaves a measurement gap. The goal of the heart failure and low back pain EBCMs is to evaluate a clinician's performance by assessing the cost of services related to a defined episode of care for a beneficiary with whom the clinician has a longitudinal relationship as determined by the triggering and confirming claims**.**

Comment: A few commenters expressed concern about the reliability of the proposed Heart Failure EBCM, noting that the measure did not meet the "high" reliability threshold at the TIN or TIN-NPI level. The commenters shared their belief that the EBCM reliability levels at 20 attributed patients are too low for measures used to adjust payments for clinicians. A commenter expressed concern that relying on a measure with only moderate reliability could lead to misleading conclusions about actual differences in performance.

Response: We recognize the commenters' concerns regarding the heart failure EBCM 20-episode volume threshold. However, we disagree that the 20-episode minimum is an inappropriate volume of cases for determining ASM cost performance category scores. An EBCM 20-episode threshold is consistent with the established episode threshold finalized for MIPS at § 414.1350(c)(6) for the EBCM.

As we discussed in the CY 2018 PFS final rule (82 FR 53697 through 53699), increasing the case minimum to improve measure reliability would reduce the number of clinicians assessed by the measure. A higher case minimum would, therefore, limit the scoring of EBCMs to larger group practices with sufficient case volume at the expense of individual providers who are the focus of ASM. We believe that an EBCM 20-episode threshold remains aligned with other CMS programs and will reliably, just like in the QPP program, measure ASM participants on cost performance.

Comment: A commenter did not support the proposed heart failure EBCM, noting concerns that the measure is narrowly defined and may not capture potential savings from efficient team-based care. The commenter also expressed concern that the proposed attribution to individual ASM participants is not patient-centered and may not recognize the efficiencies of team-based care.

Response: We appreciate the commenters' feedback but disagree that the heart failure EBCM is narrowly defined. The heart failure EBCM is designed to capture a wide spectrum of care events that occur once an episode is triggered and that are appropriately attributable to a TIN or TIN/NPI. It includes but is not limited to inpatient admissions, outpatient follow-up, medication management, diagnostic testing, and post-acute care. We also disagree that the cost EBCM, though measured at the individual level, would not recognize the efficiencies of team-based care. The EBCM reflects costs from any provider rendering an included service for an attributed beneficiary—centering the beneficiary at the heart of the measure. Therefore, efficiencies in team-based practices such as reducing duplicative services could potentially improve the ASM participant's EBCM score.

Comment: A few commenters expressed concern that the proposed heart failure EBCM does not reflect the quality of care provided by ASM participants. A commenter recommended CMS to align quality and cost scoring to prevent duplicative accountability under the heart failure EBCM, noting that the proposed quality measures include patients younger than 65, while the cost measure applies only to those older than 65. A commenter expressed concern that CMS does not account for how changes in spending and utilization may impact quality. Another commenter recommended that CMS collaborate closely with prospective ASM participants to identify measures that accurately reflect savings.

Response: We appreciate the commenters for their feedback. However, we disagree that the proposed heart failure EBCM is not aligned with the quality of care provided to participants. We believe

that the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with heart Failure (MIPS Q492) quality measure as discussed in section III.C.d.2.(b).(i) of this final rule would account for the inappropriate withholding of care in an effort for a participant to improve their cost ASM performance category score. Though we understand that the inclusion and exclusion criteria for the quality and cost measures may differ, taken individually both collective measure sets are appropriate for assessing heart failure quality of care and its associated costs. We are aligning the approach used in MIPS to reduce burden and ensure alignment across CMS programs. We disagree that the EBCMs would not reflect opportunities for findings savings and we note that the EBCMs have already undergone extensive with interested parties input, including specialty societies and technical expert panels.

Comment: A few commenters expressed concern that ASM participants may not be able to control all costs included in the proposed heart failure EBCM such as emergency department visits or post-acute care decisions made by other clinicians. Another commenter shared their belief that the heart failure EBCM could potentially penalize clinicians for poor performance even when they provide care that adheres to evidence-based clinical guidelines and is in the best interest of the patient. A commenter shared their concern that the proposed EBCM has limited the ability to distinguish between spending within, and outside of the clinician's control. Another commenter expressed concerns about the inclusion of Part D medications within the heart failure EBCM, noting that varied access to prescription medications can cause fluctuations in the cost of care.

Response: We appreciate the commenters' feedback, but we disagree that the heart failure EBCM penalizes clinicians for high costs beyond their control, or for providing care adhering to evidence-based guidelines in the best interest of the patient. The heart failure EBCM is designed to reflect the clinical appropriateness of care. The EBCM also accounts for a variety of clinically appropriate care variations, and necessary treatments. Though we acknowledge that not every care decision is controlled by the attributed participant by including services initiated by other clinicians, the measure appropriately incentivizes specialists to coordinate care and manage transitions to reduce avoidable, duplicative, fragmented and costly services. The EBCM measure specifications include all services that are included in the measure. Those services were selected as part of the scope of longitudinal heart failure chronic condition management in consultation with specialty societies and practices. While Part D costs are

included within the episode, we note that Part D costs are winsorized such that extreme observations at and above the 98th percentile are excluded from the EBCM's calculations. We believe it is important to include Part D spending because Part D spend oftentimes represents a significant portion of episode's total cost. The inclusion of Part D spending creates participant accountability for that portion of spend. Furthermore, including Part D spend prevents any inappropriate cost shifting that may occur if Part D spend is excluded such that participants were incentivized to move Part B spend to Part D spend to artificially deflate Part B measured spending.

Comment: A few commenters expressed concerns about the proposed attribution methodology for the heart failure EBCM. A commenter recommended that CMS continue to refine the heart failure EBCM attribution methodology to better account for the nuances between cost and clinical appropriateness.

Response: We appreciate the commenters' feedback, but we disagree that the heart failure EBCM relies on a flawed attribution methodology. The heart failure EBCM is built upon a two-stage process to identify clinically appropriate patients receiving longitudinal heart failure care. A heart failure episode is only attributed to an ASM participant if two Part B Physician/Supplier (Carrier) claims are billed by the same ASM participant within 180 days of one another. The pair of services must include a trigger claim and confirming claim from any of the set of clinically relevant outpatient CPT/HCPCS codes and services when accompanied by an ICD-10 diagnosis code indicating heart failure. This sophisticated methodology ensures that only beneficiaries receiving longitudinal heart failure management from the same ASM participant will trigger an episode. We did not consider refinements to the attribution methodology to remain aligned with the existing measure specifications under MIPS and to ease participant burden.

Comment: Several commenters expressed concern that the heart failure EBCM does not capture the clinical complexity of the patients with heart failure, which can impact episode costs. A few commenters shared their belief that the proposed EBCM does not adjust for many social and economic factors that affect the number and types of services patients receive or improvements in care access that could increase costs but also improve outcomes, which could significantly disadvantage clinicians serving more complex patients. A few commenters recommended that CMS continue to refine risk adjustment to better reflect the nuances between cost and clinical appropriateness, particularly for high-risk populations such as older adults with multiple comorbidities. A few commenters requested that CMS publish more

details on how patient complexity and comorbidities will be incorporated into risk adjustment and clarify how risk adjustment differs between the MIPS/MVPs EBCM and the ASM version of the EBCM. A commenter recommended that certain cases be excluded or separately benchmarked, including advanced therapies, cardiogenic shock/ECMO, multi-organ failure, high-risk electrophysiology/device dependence, active transplant evaluation (where diagnostic intensity and consultative services dominate spending), and end-of-life care with hospice election during the episode window.

Response: We appreciate the commenters for their concerns that the low heart failure EBCMs do not reflect patient complexity, however, we disagree. The heart failure EBCM's sophisticated risk adjustment methodology accounts for patient complexity, and comorbidities outside of the participant's control. The EBCM risk adjustment methodology uses clinical factors such as age, comorbidities, recent hospitalizations and other relevant conditions to standardize costs. The heart failure risk adjustment methodology employed in ASM is the same methodology used in MIPS/MVPs EBCM. Additionally, the exclusion criteria are designed to remove unique groups of patients or episodes from the measure calculation in cases where it may be impractical or unfair to compare the costs of caring for these patients to the costs of caring for the cohort at large. Heart failure EBCM exclusions include amyloidosis, congenital heart disease, high-output heart failure, hypertrophic cardiomyopathy, prior and/or recent left ventricular assist device (LVAD), prior and/or recent heart transplant, peripartum cardiomyopathy, and other infiltrative disease. While the EBCM does not account for all social risk factors in its risk adjustment methodology, we stress that beneficiary social and economic characteristic and challenges faced by small or solo practices are addressed in the complex patient scoring adjustment section III.C.d.4.(3) of this final rule and small practice scoring adjustment in section III.C.d.4.(4) of this final rule. We believe that both the complex patient scoring adjustment and the small practice scoring adjustment properly addresses the realities those ASM participants face because those adjustments are simpler and do not require any additional participant reporting.

Comment: A commenter recommended that CMS provide actionable data and definitions and identify ways to improve cost performance on the heart failure EBCM.

Response: We appreciate the commenters for their recommendation to provide actionable data and methods to improve performance. We are exploring ways to provide participants with the right data at the right intervals to assist their performance in ASM.

After consideration of public comments, we are finalizing as proposed at § 512.730(b)(1) the use of the heart failure EBCM to score the cost ASM performance category for the ASM heart failure cohort.

(d) Cost Measure for ASM Low Back Pain Cohort

For the ASM low back pain cohort, we proposed at § 512.730(b)(2) to utilize the low back pain EBCM to determine an ASM low back pain participant's cost ASM performance category score.[258] The low back pain EBCM evaluates a participant's risk adjusted and specialty-adjusted cost to Medicare for patients receiving medical care to manage and treat low back pain. We proposed the low back pain EBCM, in part, to align with the Rehabilitative Support for Musculoskeletal Care MVP (88 FR 80002 through 80007; 89 FR 99050 through 990054). We also believe this chronic condition EBCM appropriately captures the costs of services that are clinically related to the participant's role in managing the longitudinal care during a low back pain episode.

We believe that the use of the low back pain EBCM would help increase accountability on spending and limit low -value care related to low back pain. Low back pain is highly prevalent and a high driver of spending. For example, an estimated 20 percent of people living in the United States experience low back pain,[259] and a 2020 study found that low back and neck pain contributed the most to health care spending among 154 mutually exclusive diagnoses, at $134.5 billion in 2016.[260] Other studies have also found large increases in resource use for low backpain despite only modest increase in its prevalence and little improvement in patient outcomes,[261] [,262] [,263] which underscores the need for more precise measure of resource use and quality of care. Given these findings, we believe the low back pain EBCM would be an

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[258] https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.
[259] Will, Joshua Scott, David Bury, and John Miller, "Mechanical Low Back Pain." American Academy of Family Physicians 98(7) (2018): 421-428.
[260] Dieleman, Joseph, Jackie Cao, and Abby Chapin, "US Health Care Spending by Payer and Health Condition, 1996-2016." JAMA Network 323(9) (2020): 863-884. doi:10.1001/jama.2020.0734.
[261][261] Luo, Xuemei, Ricardo Pietrobon, Shawn Sun, Gordon Liu, and Lloyd Hey, "Estimates and Patterns of Direct Health Care Expenditures Among Individuals With Back Pain in the United States." Spine 29(1) (2004): 79-86. doi:10.1097/01.BRS.0000105527.13866.0.
[262] Deyo, Richard, Sohail Mirza, Judith Turner, and Brook Martin, "Overtreating Chronic Back Pain: Time to Back Off?" J Am Board Fam Med 22(1) (2009): 62-68. doi:10.3122/jabfm.2009.01.080102.
[263] Norman Marcus Pain Institute, "Pain Facts." Last updated 23 January 2012. https://www.normanmarcuspaininstitute.com/tag/neck-and-shoulder-pain/.

appropriate measure by which to accurately determine resource use related to low back pain and compare cost-related performance across ASM low back pain participants.

We sought comments on the proposed use of the low back pain EBCM at § 512.730(b)(2) to determine the cost ASM performance category score for the ASM low back pain cohort.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concerns about the proposed low back pain EBCM for ASM participants, noting low reliability thresholds at the individual clinician level. The commenters noted that the reliability levels for TIN/NPIs with 20 or more attributed patients are too low for measures used to adjust payments for clinicians.

Response: We recognize commenters' concerns regarding the low back pain EBCM 20-episode threshold. However, we disagree that the 20-episode minimum is an inappropriate volume of cases for determining ASM cost performance category scores. An EBCM 20-episodethreshold is consistent with the established case volume finalized for MIPS at § 414.1350(c)(6) for EBCMs. As we discussed in the CY 2018 PFS final rule (82 FR 53697 through 53699), increasing the case minimum to improve measure reliability would reduce the number of clinicians assessed by the measure. A higher case minimum would, therefore, limit the scoring of EBCMs to larger group practices with sufficient case volume at the expense of individual providers who are the focus of ASM. We believe that a minimum EBCM 20-episodethreshold remains aligned with other CMS programs and will reliably, just like in the QPP program, measure ASM participants on cost performance.

Comment: A few commenters expressed concern that the proposed low back pain EBCM may not align with the quality measures for the ASM low back pain cohort or that the low back pain EBCM may not accurately reflect the quality of care provided by ASM participants. A few commenters shared their concern that assessing cost without considering outcomes could create unintended incentives, such as encouraging clinicians to avoid complex patients, limiting necessary care, or promoting pharmacologic or surgical interventions that may not be appropriate. A commenter recommended that CMS develop quality and cost measures in tandem to create a single value measure that integrates both dimensions. Another

commenter suggested CMS to collaborate closely with prospective ASM participants to identify measures that meaningfully reflect savings.

Response: We appreciate the commenters for their feedback. However, we disagree that the proposed low back pain EBCM is not aligned with the quality of care provided to participants. For example, the low back pain Functional Status Change for Patients with Low Back Impairments (MIPS Q220) score would lower if an ASM participant attempted to inappropriately limit necessary care to improve their cost performance score. We further stress that the EBCM's risk adjustment methodology accounts for patient acuity and complexity. The EBCM risk adjustment methodology uses clinical factors such as age, comorbidities, recent hospitalizations and other relevant conditions to standardize costs. We did not consider merging quality and cost measurement into a single value because we believe that measuring them separately ensures direct accountability for performance on quality and cost. We note that the low back pain EBCM has already undergone extensive interested parties input, including with specialty societies and technical expert panels. Further, we believe that the EBCM performance can help ASM participants identify areas for potential savings.

Comment: Several commenters expressed concern that ASM participants may not control all costs included in the proposed low back pain EBCM, such as patient emergency department visits or post-acute care decisions made by other clinicians. A commenter recommended that CMS consider separating spending into categories, distinguishing between expenditure on avoidable services controlled by ASM participants and all other costs. A commenter also expressed concern that holding ASM participants, particularly proceduralists, accountable for care beyond their control is not clinically appropriate and may result in unjust penalties. Another commenter recommended CMS clarify which services are included in the low back pain EBCM.

Response: We appreciate the commenters for expressing their concern. However, we disagree and believe that including services performed in the emergency room or post-acute care decisions made by other clinicians is vital to incentivizing ASM participants to provide upstream care management to reduce unnecessary services. Though we acknowledge that not every care decision is controlled by the ASM participant, including services initiated by other clinicians appropriately incentivizes specialists to coordinate care and manage transitions to reduce avoidable, duplicative, fragmented and costly services.

This is especially the case for proceduralists for whom we would like to extend accountability for their management of beneficiaries with chronic conditions beyond the procedure they initiate. We also note that for a beneficiary to be attributable to a proceduralist the triggering event must include an ICD-10 diagnosis code indicating low back pain as well as a confirming code within 60 days. Meeting the requirements set forth through this attribution process suggests that a longitudinal care relationship that between the proceduralist and beneficiary. We refer commenters to the cost measure codes lists available on the 2024 MIPS cost performance category resources for a comprehensive EBCM services list.[264]

Comment: A commenter did not support the proposed low back pain EBCM, noting concerns that the measure is narrowly defined and may not capture potential savings from efficient team-based care. The commenter also expressed concern that the proposed attribution to individual ASM participants is not patient-centered and may not recognize the efficiencies of team-based care.

Response: We appreciate the commenters' feedback but disagree that the low back pain EBCM is narrowly defined. The low back pain EBCM is designed to capture a wide spectrum of care events that occur once an episode is triggered. And that are appropriately attributable to a TIN or TIN/NPI The EBCM includes inpatient admissions, outpatient follow-up, medication management, diagnostic testing, and post-acute care services. We also disagree that the cost EBCM, though measured at the individual would not recognize the efficiencies of team-based care. The EBCM reflects costs from any provider rendering an included service. Therefore, efficiencies in team-based care such as the reduction of duplicative services will improve the ASM participant's EBCM score.

Comment: A commenter expressed concern that services provided by anesthesiologists, including pain medicine physicians who treat patients with lower back pain, may not be captured by the existing cost measure methodology for the low back pain EBCM. The commenter expressed concern that CMS' reliance on the remaining single ASM performance category for anesthesiologists, quality, could undermine a comprehensive assessment of how clinicians or their groups deliver care to Medicare patients.

Response: We appreciate the commenters for sharing their concerns. However, we disagree with their assessment that an anesthesiologist is not likely to meet the cost performance category minimum

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[264] https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.

requirements to receive a cost performance category score. Selection into ASM requires that a participant must have already met the 20-episodethreshold from the calendar year determining performance year eligibility. The likelihood that the participant would also meet the case 20-episode threshold during the given ASM performance year, would be high. Therefore, the participant would receive a cost score on any of the quality measures for which they meet those minimum data and submission requirements as described in sections III.C.d.(2).(g) and III.C.2.d.(2).(h) of this final rule.

Comment: A few commenters expressed concerns about the proposed attribution methodology for low back pain EBCM, noting concerns that the attribution methodology would identify the correct clinician, particularly for low back pain, where care is often fragmented and patients may see multiple clinicians. A commenter expressed concern that most potential ASM participants would have a low volume of EBCM cases, which may not accurately represent their overall practice.

Response: We appreciate the commenters for expressing their concerns regarding the low back pain EBCM attribution methodology. However, we disagree with the commenters' concerns. The low back pain EBCM requires that a triggering event must include an ICD-10 diagnosis code indicating low back pain as well as a confirming code within 60 days from the same Tin/NPI—or in ASM's case the ASM participant. This ensures that only beneficiaries with a diagnosis of low back pain are included in the measure. By assigning accountability for costs to a provider that initiated a low back pain episode, we have created the incentive structure to reduce fragmented care. Additionally, to receive a cost score an ASM participant must meet the 20 episode threshold. As discussed earlier in this section of this final rule, a 20-episode threshold is consistent with the established case volume to score MIPS participants at § 414.1350(c)(6) and with ASM's participant eligibility criteria.

Comment: A few commenters expressed concern that the proposed low back pain EBCM may not capture the clinical complexity of the patients with low back pain, which could impact episode costs. A few commenters noted the difference between general low back pain and more complex cases, noting that comorbidities can affect treatment choices. A commenter requested that several cases be excluded or stratified, such as those involving malignancy, infection, fracture, major structural abnormalities, urgent neurologic compromise, prior spine surgery, implanted hardware (including spinal cord stimulators or fusion constructs), failed comprehensive conservative care with documented non-response to multimodal

therapy, and non-spinal mimics. Another commenter noted that the model does not adjust for many social and economic factors that affect the types and number of services patients receive, which could disadvantage ASM participants serving patients from lower income communities. Another commenter recommended that attribution and benchmarks account for issues specific to smaller practices.

Response: We appreciate the commenters for their concerns that the low back pain EBCMs does not reflect patient complexity, however, we disagree. The low back pain EBCM's sophisticated risk adjustment methodology accounts for patient complexity, and comorbidities outside of the participant's control. The EBCM risk adjustment methodology uses clinical factors such as age, comorbidities, recent hospitalizations and other relevant conditions to standardize costs. Additionally, the exclusion criteria are designed to remove unique groups of patients or episodes from the measure calculation in cases where it may be impractical or unfair to compare the costs of caring for these patients to the costs of caring for the cohort at large. Low back pain exclusions include cauda equina syndrome, spinal infection, osteoporotic compression fracture, myelopathy, trauma, and spinal neoplasms. Any additional exclusions would diverge from the EBCMs structure as used by MIPS, potentially increasing administrative burden to have model-specific modifications to the measure's specifications. While the EBCM does not account for all social risk factors in its risk adjustment methodology, we stress that beneficiary social and economic characteristic and challenges faced by small or solo practices are addressed in the complex patient scoring adjustment section III.C.2.e.e(3) of this final rule and small practice scoring adjustment in section III.C.2.e.2d.e(4) of this final rule. We believe that both the complex patient scoring adjustment and the small practice scoring adjustment better address the realities those participants face because those policies are simpler and do not require any additional participant reporting.

Comment: A commenter recommended that CMS provide actionable data and definitions and identify ways to improve performance on the low back pain EBCM.

Response: We appreciate the commenters for their recommendation to provide actionable data and methods to improve performance. We are exploring ways to provide participants with the right data at the right intervals to assist their performance.

After consideration of public comments, we are finalizing as proposed at § 512.730(b)(2) the use of the low back pain EBCM to score the cost ASM performance category for the ASM low back pain

cohort.

(e) Removal and Addition of Cost Measures

We intend to avoid making significant changes to the cost measure over the ASM test period. However, we proposed at § 512.730(c) to add or remove measures through notice and comment rulemaking as discussed at § 512.730(c) if we believe refinements to the measure set are necessary. We may propose to add or remove measures in response to relevant public comments, recommendations from participants and their collaborators, new CMS program activities, or significant changes to the included measures. Because the cost measures currently proposed are all part of MIPS, any updates CMS applies to the measures within MIPS would be incorporated into the cost ASM measure sets accordingly.

We solicited comments on our proposed approach at § 512.730(c) for adding or removing cost measures if necessary.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed at § 512.730(c).

(f) Minimum Case Requirements

Like under MIPS, as specified in § 414.1350(c)(6) (88 FR 79346 through 79348), we proposed at § 512.730(d) that an ASM participant must have at least 20 attributed episodes (that is, cases) at the TIN/NPI level during an ASM performance year for the ASM participant to receive a score on the applicable EBCM. A participant with an unscored EBCM would also remain unscored in their ASM cost performance category score, resulting in a neutral payment adjustment for the applicable ASM payment year because the participant is required to have an ASM cost performance category score to receive a final score as discussed in section III.C.2.e.(2)(b) of this final rule. As discussed in section III.C.2.c.(3)(b) of this final rule, we believe that setting a minimum volume threshold during the calendar year 2 years prior to the applicable ASM performance year for the heart failure EBCM and the low back pain EBCM as part of ASM participant eligibility criteria would mean that ASM heart failure participants and ASM low back pain participants would be likely to meet the same episode case minimum during each ASM performance year.

We sought comment on the proposed case minimum of 20 attributed episodes for all cost measures at § 512.730(d) used to score the cost ASM performance category.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern with the proposed 20-episode threshold for the ASM EBCMs, noting that a small denominator for patient attribution may not produce a reliable performance score. A few commenters recommended increasing volume thresholds to better account for statistical variation. Specifically, a commenter suggested that clinicians should not be scored on the heart failure EBCM unless they have at least 50 attributed episodes, or if the number of episodes meets the reliability threshold of at least 0.8, whichever is greater. A few commenters shared their concern that even a single outlier case or event could disproportionately impact performance results and unfairly penalize clinicians who treat patients that are frail or vulnerable with complex medical conditions.

Response: We recognize the commenters' concerns regarding the heart failure and low back pain EBCM 20-episode threshold. However, we disagree that it is an inappropriate volume of cases for determining cost ASM performance category scores. An EBCM 20-episode threshold is consistent with the established minimum case volume finalized for MIPS at § 414.1350(c)(6) for both the heart failure and low back pain EBCMs. As we discussed in the CY 2018 PFS final rule (82 FR 53697 through 53699), increasing the case minimum upwards of a figure like 50 episodes would reduce the number of clinicians assessed by the measure. This would, therefore, limit the scoring of EBCMs to larger group practices with sufficient case volume at the expense of individual providers who are the focus of ASM. We believe that a minimum EBCM 20-episode threshold remains aligned with other CMS programs and will reliably, just like in the QPP program, measure ASM participants on cost performance. We also note that Part D costs are winsorized such that extreme observations at and above the 98th percentile are excluded from the EBCM's calculations.

After consideration of public comments, we are finalizing at § 512.730(d) the proposed case minimum of 20 attributed episodes for all cost measures used to score the cost ASM performance category as proposed.

(g) Cost Measure Achievement Points and Cost ASM Performance Category Scoring

(i) Cost Measure Achievement Points

We proposed to follow a similar methodology for establishing and assigning measure achievement points as is used by MIPS. We proposed at §§ 512.730(e)(1)(i) that for each cost measure attributed to an ASM participant, CMS assigns the ASM participant 1 to 10 achievement points (including partial points) based on the ASM participant's performance on the cost measure during the ASM performance year compared to the cost measure's benchmark. Achievement points are awarded based on which benchmark range the ASM participant's performance on the measure is in.

We sought comment on the proposed methodology for establishing and assigning measure achievement points for the cost ASM performance category as proposed at §§ 512.730(e)(1)(i).

We did not receive specific comments on the proposed provisions at §§ 512.730(e)(1)(i) and are, therefore, finalizing as proposed.

(ii) Benchmarking

We proposed at § 512.730(e)(2)(i) that CMS bases cost measure benchmarks on cost measure performance of ASM participants during the ASM performance year. To develop reliable cost measure benchmarks, we proposed at § 512.730(e)(2)(i)(A) that each benchmark must have a minimum of 20 ASM participants who meet the minimum case volume specified at § 512.730(d) for CMS to determine a benchmark for the cost measure. We proposed at § 512.730(e)(2)(i)(B) if a benchmark is not determined for a cost measure, then the measure would not be scored.

We proposed at § 512.730(e)(2)(ii) to score each EBCM using 10 benchmark ranges based on the median (that is, 50th percentile) cost of all ASM participants attributed the relevant measure plus or minus standard deviations. We proposed at § 512.730(e)(2)(ii) to center the 10 benchmarks ranges at half the measure achievement points achievable for each EBCM. Given that the measure achievement points range from 1 to 10, the ASM participant with the median cost would be assigned 6 EBCM measure achievement points. We would then determine the score ranges applicable to each of the 10 measure achievement points based on standard deviations above and below the median score. We proposed to calculate these benchmark ranges separately for each EBCM.

We believe the proposed benchmark ranges, calculated using the median and centered around half of the available points for each EBCM would be dynamic and responsive to changes in average spending per episode assessed by cost measures and performance thresholds for each ASM performance year. We would update the median and standard deviations used to determine cutoffs for benchmark ranges so that they are based on performance within the ASM performance year. To determine the benchmark ranges, we would adhere to the following principles: (1) determine benchmark ranges according to the distribution of the EBCM averages; and (2) ensure distribution of measure achievement points for cost measures is reflective of overall program performance. We refer readers to Table B-D5 for an example of how the proposed cost scoring methodology could be implemented for a specific cost measure.

TABLE B-D5: EXAMPLE OF IMPLEMENTATION OF THE COST SCORING METHODOLOGY FOR ASSIGNMENT OF ACHIEVEMENT POINTS FOR PERFORMANCE ON THE HEART FAILURE COST MEASURE

Benchmark Range	Points	Illustrative Methodology for the Bottom of the Benchmark Range ($)
Benchmark Range 1	1 – 1.9	Median cost + (2.5 × standard deviation)
Benchmark Range 2	2 – 2.9	Median cost + (2 × standard deviation)
Benchmark Range 3	3 – 3.9	Median cost + (1.5 × standard deviation)
Benchmark Range 4	4 – 4.9	Median cost + (1 × standard deviation)
Benchmark Range 5	5 – 5.9	Median cost + (0.5 × standard deviation)
Benchmark Range 6	6 – 6.9	Median cost + (0 × standard deviation)
Benchmark Range 7	7 – 7.9	Median cost - (0.5 × standard deviation)
Benchmark Range 8	8 – 8.9	Median cost - (1 × standard deviation)
Benchmark Range 9	9 – 9.9	Median cost - (1.25 × standard deviation)
Benchmark Range 10	10	Median cost - (1.5 × standard deviation)

We proposed at § 512.730(e)(2)(ii) to award up to 10 measure achievement points for each EBCM based on which benchmark range an ASM participant's EBCM average corresponds using the following formula:

> EBCM Achievement Points = Benchmark Range # + [(measure score, expressed as a dollar amount−bottom of benchmark range)/(top of benchmark range−bottom of benchmark range)].

This scoring methodology for cost measures would align the assignment of measure achievement points for cost measures so that participants with costs near the measure's median (that is, 50th percentile) would not receive a disproportionately low score. Rather participants with costs near the median would receive an individual EBCM score clustered closer to the median.

We also considered using even decile benchmark ranges based on the distribution of each EBCM score. This alternative approach, however, would mean that ASM participants with EBCM averages near

the 50th percentile would receive lower cost measure scores. Given the distribution of EBCM averages proposed for ASM, we believe even decile benchmark ranges would create narrow benchmark deciles that would result in a less accurate assessment of cost performance. For these reasons, we believe it would be more appropriate to use the proposed episode-based cost benchmarking and measure scoring methodologies.

We solicited comments on our proposed approach for calculating EBCM benchmarks and scoring each cost measure, as well as all alternatives considered.

The following is a summary of the comments we received and our responses.

Comment: A commenter recommended the use of prospective peer-grouped benchmarks with case-mix stratification and regional price standardization and stated their belief that such benchmarks could potentially limit cost differences in high-acuity versus community practices.

Response: We appreciate the commenter for sharing their recommendation that we use prospective peer-grouped benchmarks with case-mix stratification and regional price standardization to limit cost differences in high-acuity versus community practices. We note that EBCMs do use standard, Medicare allowed amounts, in their calculations. However, we disagree with the recommendation to use prospective peer-grouped benchmarks because of our overarching goal when calculating benchmarks to follow a similar methodology as is used by MIPS so that most ASM participants would be familiar with the benchmarking approach. Though we did not consider this approach to benchmarking, if we did, we would do so in future notice-and-comment rulemaking.

Comment: A few commenters recommended that CMS clarify how benchmarking will be applied when the same measure is used in MIPS and in ASM, given the distinct clinician populations. The commenters suggested that CMS compare the benchmarks between MIPS and ASM to illustrate any differences. A commenter expressed concern that the heart failure EBCM was originally developed across multiple specialties and recommended selecting the benchmark that is most favorable to ASM participants to ensure fair and equitable scoring.

Response: We appreciate the commenters for sharing their recommendation to clarify our benchmarking approach when it differs from other CMS cost benchmarking methodologies like in MIPS. We stress that the ASM benchmark ranges will only be calculated using ASM participant EBCM data,

which would allow for fair comparisons of performance of ASM participant performance. Any modifications at the end of the performance year to the methodology to benefit some participants would hurt other participants. We further clarify that ASM benchmarks are calculated separately for each cohort.

Comment: A commenter did not support the proposed methodology to calculate benchmarks for ASM EBCMs. For the heart failure EBCM a commenter expressed concern that benchmarking based solely on cardiologists, particularly at the individual clinician level, could bias rankings and result in inconsistent or misleading scores,. A commenter recommended that CMS stratify the heart failure EBCM results by ejection fraction phenotype. The commenter also recommended CMS develop a more granular, specialty-specific benchmarking approach that reflects clinical realities and avoids applying measures validated in one population to another with different practice patterns and patient profiles.

Response: We appreciate the commenter for their concern, however, we disagree that the benchmarking approach as proposed would result in inconsistent scores because by determining benchmarks based off cardiologists' performance, we are creating benchmark sets calculated from ASM participants' peers. Further, we did not consider stratifying the cost cohort by heart failure type because EBCM scores and data are not stratified by condition so we would be unable to calculate benchmarks segmented by condition. Additionally, we disagree that the EBCMs apply measures validated in one population onto another. The EBCMs were developed for specific specialty types and to adjust for fairer comparison based on patient profiles include a sophisticated risk adjustment methodology as discussed earlier in this section. .

After consideration of public comments, we are finalizing at § 512.730(e)(2)our benchmarking policies that base cost measure benchmarks on cost performance during the ASM performance year, and the formation of 10 benchmark ranges based on median cost and standard deviations as proposed.

(iii) Calculation of the Cost ASM Performance Category Score

We proposed at § 512.730(e)(3) that the cost ASM performance category score would be calculated as the sum of the total number of measure achievement points earned by the ASM participant from each required measure divided by the total number of available measure achievement points for each required cost measure, not to exceed 100 percent, for ASM heart failure participants or ASM low back pain participants. As discussed in section III.C.2.d.(3)(g) of this final rule, we proposed at §

512.730(e)(3)(i) that an ASM participant who does not have 20 attributed episodes during an ASM performance year would not receive a cost ASM performance category score and would not receive a final score as discussed in section III.C.2.e.(b) of this final rule.

We believe that this proposed cost ASM performance category score ensures that ASM participants can be appropriately held accountable on spending related to ASM's targeted chronic conditions. This proposed cost ASM performance category scoring methodology means that the cost ASM performance category would be equivalent to the score for the heart failure EBCM for ASM heart failure participants and the low back pain EBCM for ASM low back pain participants since each participant group is only scored on 1 cost measure.

We proposed at § 512.730(e)(3)(ii) that if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the ASM participant's cost performance category score and a cost performance category score is not calculated.

We proposed at § 512.730(e)(3)(ii)(A) to define "significant changes or errors" regarding instances in which the cost measure score could not be calculated as changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

We proposed at § 512.730(e)(3)(ii)(B) that significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, changes to codes (such as ICD-10, CPT or HCPCS codes), the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications.

We also proposed at § 512.730(e)(3)(ii)(C) that we would empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We believe these proposed policies would appropriately adapt the proposed cost ASM performance category scoring policies so that ASM

participants would not be penalized for changes or errors in the measure and associated submitted data that would be outside the control of the ASM participant.

We solicited comments on our proposed methodology for calculating the cost ASM performance category score.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concerns on the proposed cost scoring for the ASM EBCMs, noting misaligned incentives may discourage specialist participation. The commenters shared their belief that inherently higher costs of complex cases driven by patient severity, rather than inefficiencies or poor quality, combined with the emphasis on cost without appropriate risk adjustments, and severe financial consequences could discourage skilled specialists from participating in ASM and from providing care in resource-intensive but clinically appropriate settings like hospitals and rural facilities, ultimately limiting patient access to necessary care. A commenter suggested CMS to gradually phase in cost accountability, with safeguards to avoid unintended penalties and support the goal of increasing specialist participation in value-based care. Another commenter expressed concern that cost benchmarks for ASM, if set without specialty input, may undervalue the complexity and safety needs of image-guided spinal interventions, could impact clinical decisions and reduce access to essential, minimally invasive treatments, potentially leading to increased opioid use or unnecessary surgery, contradicting CMS' goals of improving quality and reducing costs

Response: We appreciate the commenters for expressing their concerns on ASM scoring of EBCMs, however, we disagree that the cost category creates improper incentives. We stress that the EBCMs use an advanced risk adjustment methodology so that cost comparisons are not raw cost versus cost. But rather, risk standardized cost versus their peers' costs treating similar patients. We did not consider phasing in cost accountability because our ASM cost performance category closely mirrors the cost performance category as defined in MIPS, so specialists should be familiar with this measure. Additionally, our benchmarking methodology uses risk adjusted costs so as not to penalize or reward participants on patient complexity or lack thereof.

Comment: A few commenters generally expressed concerns on the Cost ASM scoring policies. A commenter expressed concern that including spending on necessary services in EBCMs could inadvertently reward clinicians for reducing spending on essential care, potentially leading to worse patient outcomes that may not be reflected in quality measures, noting that average spending on patients could increase due to factors outside a clinician's control, such as rising drug prices or services ordered by other physicians, which could unfairly penalize clinicians. Another commenter recommended that cost metrics account for the influence of primary care or consider exclusion criteria for patients not primarily managed by specialists, to ensure fair attribution and avoid penalizing specialists for outcomes beyond their control.

Response: We appreciate the commenter for their concerns on Cost ASM scoring policies, however, we disagree that the cost ASM scoring policies reward clinicians for reducing spend on essential care. Both the heart failure and low back pain quality measure sets, as discussed earlier in this section, contain measures whose performance may lower if participants choose to inappropriately withhold care. We note that the EBCMs do not compare participants to prior year spending, rather they are scored based off of performance relative to their cohort. We did not consider adjusting the EBCM for the influence of primary care because the EBCM has already undergone extensive review by multiple specialty societies and clinicians. Lastly, EBCMs are only attributed to specialists if they render a triggering and confirming service with a corresponding ICD-10 code. We believe that that threshold is high enough to assume that ASM participants with EBCMs assigned to them are active in managing the care of their patients.

Comment: A commenter suggested establishing clear performance benchmarks for EBCMs to guide positive and negative adjustments, allowing clinicians to make informed practice and investment decisions with assurance that their performance will be evaluated fairly. A commenter further recommended that CMS publish the cost measure specifications used in the model along with the claims used for calculating the measures to support transparency and effective performance monitoring.

Response: We appreciate the commenter for their recommendation. However, we disagree with their recommendation because positive and negative payment adjustments are based off of numerous factors beyond the cost performance category. Therefore, it would be improper to set a performance threshold in the cost benchmarking category. We also note that all EBCM measure specifications are

publicly available on the CMS website.

After consideration of public comments, we are finalizing as proposed at § 512.730(e)(3) that the cost ASM performance category score would be calculated as the sum of the total number of measure achievement points earned by the ASM participant from each required measure divided by the total number of available measure achievement points for each required cost measure, not to exceed 100 percent, for ASM heart failure participants or ASM low back pain participants. We did not receive public comments on the provisions at § 512.730(e)(3)(ii), § 512.730(e)(3)(ii)(A), § 512.730(e)(3)(ii)(B), and § 512.730(e)(3)(ii)(C) and therefore, we are finalizing as proposed.

(4) Improvement Activities ASM Performance Category

The requirements in the improvement activities ASM performance category aim to improve care coordination, increase collaboration between specialty and primary care, and better address upstream drivers of health for patients. These activities support the model goals to improve quality care as measured through a focused measure set relevant to ASM participants. They also support prevention efforts that incentivize ASM participants to ensure that their patients have a regular source of primary care and are screened to help identify early signs of chronic conditions. The improvement activities ASM performance category would be used to determine a potential scoring adjustment to the final score. We refer readers to sections III.C.2.e.(1) and III.C.2.e.(5) of this final rule for details on how the scores in the improvement activities scoring adjustment would be applied to the ASM final score.

(a) Background

The improvement activities ASM performance category provides ASM participants with an opportunity to support broader improvements in health care delivery. Improvement activities originated in MIPS to improve care coordination, foster beneficiary engagement, and advance population health management as described at § 414.1355. ASM leverages this structure and proposes at § 512.705 to define “improvement activities” as activities relating to care coordination, integration of specialty and primary care, and addressing health-related social needs (HRSN) of patients.

Care coordination helps to ensure that all healthcare providers involved in a patient's care have appropriate access to relevant patient information and are working towards the same care goals. The exchange of up-to-date and detailed patient information among healthcare providers can improve patient

outcomes, safety, and support clinical decision making.[265] Integration of specialty and primary care would also positively impact the patient experience. A 2022 study examining fragmentation in ambulatory care for Medicare FFS beneficiaries found that 4 in 10 beneficiaries experience highly fragmented care, with a mean of 13 ambulatory visits across seven practitioners in 1 year.[266] By providing a more seamless and coordinated approach to beneficiary care, providers reduce the need for patients to spend as much time navigating the health care system and lower any undue costs for patients that may be associated with an increased number of clinical visits and services. This approach also can prevent the worsening of disease by ensuring all parties are aware of a patient's needs, aligned with a care plan, and receiving appropriate prevention and screening services. We borrow elements from the care coordination improvement activities subcategory of MIPS to align with activities in which organizations may already be engaged.

Consistent with our model goals, we believe it is important to create a single set of achievable improvement activities that are applicable to all ASM participants. We took several steps to ensure these improvement activities are consistent with our intent to improve meaningful coordination and collaboration. We developed the measures for this ASM performance category based on our review of feedback provided in response to our RFI (89 FR 61596), interviews with interested parties, and an environmental scan of existing practice coordination activities from the Quality Payment Program and other Innovation Center models.[267]

We solicited comments on our proposed definition for "improvement activities." We did not receive specific comments on our proposed definition of "improvement activities," so we are finalizing it as proposed at § 512.705.

(b) Performance Year for Improvement Activities

Beginning with ASM payment year 2029, we proposed at § 512.735(a) that the ASM performance year for improvement activities would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the

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[265] Foy R. Meta-analysis: Effect of Interactive Communication Between Collaborating Primary Care Physicians and Specialists. *Annals of Internal Medicine*. 2010;152(4):247. doi:*https://doi.org/10.7326/0003-4819-152-4-201002160-00010*.

[266] Centers for Medicare & Medicaid Services. CMS Innovation Center's Strategy to Support Person-Centered, Value-Based Specialty Care. CMS.gov Blog. Published October 19, 2023. https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care (accessed 2/24/25).

[267] Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments.

full calendar year. We believe that setting the ASM performance year for improvement activities in this way aligns with MIPS as defined at § 414.1320 and would be easily adoptable by ASM participants. We sought comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposal to align the ASM performance year for improvement activities with MIPS, noting continuity in reporting, leveraging existing infrastructure and reducing burden.

Response: We appreciate this supportive feedback regarding the performance year alignment. We are finalizing the policy to establish the ASM performance year for improvement activities as a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year. This approach maintains consistency with existing MIPS reporting frameworks and supports operational efficiency for ASM participants and their technology vendors.

Comment: A commenter recommended CMS publish ASM improvement activities requirements with the CY 2026 final rule and include them in the existing MIPS inventory and data validation and audit spreadsheet, so clinicians can prepare and adjust workflows ahead of ASM participation in CY 2027.

Response: We appreciate the commenter's interest in the Improvement Activities (IA) requirements and specifications for ASM and their thoughtful suggestions regarding publication timing. The details provided in the final rule constitute the specifications for the IAs, and the program is designed with built-in flexibility to support practices in approaching these activities as they determine most appropriate for their clinical workflows and patient populations. We understand the interest in comprehensive guidance on improvement activity implementation and recognize the importance of supporting ASM participants in their preparation efforts. ASM will continue to evolve as we gather experience from current ASM participants. Our approach allows clinicians the autonomy to tailor an IA to their specific practice environments while meeting the model's quality improvement objectives. We intend to provide participants with additional resources on model requirements and performance category

requirements in the year leading up the model start. We intend to make these resources available on the ASM website.

Comment: A commenter expressed concern that the proposed IA requirements could force small practices to close, increase consolidation within the health care industry, and discourage specialists from treating Medicare patients.

Response: We appreciate the commenters for their concern about the improvement activities requirements. While we acknowledge that these ASM-specific requirements may be new activities that may require additional effort, we do not believe these IA requirements would force small practices to close. To support the small practices, we proposed additional policies and flexibilities in ASM, such as the small practice scoring adjustment described in section III.C.2.e.(4) of this final rule and adjusted data submission requirements at § 512.720(a)(1)(ii) to allow for the Improvement Activities to be reported at the TIN level. Also, we do not believe small practices will need to consolidate in order to meet the improvement activity requirements as we allow ample flexibility in the specifications and provide significant time for implementation as the model does not start until January 1, 2027. For these same reasons, we do not believe that the model will discourage providers from treating Medicare patients and believe that the opportunity for positive payment adjustments from the model will motivate participants.

After consideration of public comments, we are finalizing the proposed performance year for improvement activities as proposed at § 512.735(a).

(c) Improvement Activities

We proposed at § 512.735 the establishment of the improvement activities ASM performance category. We proposed at § 512.735(b) that we would evaluate ASM participants on the proposed improvement activities at § 512.735(c): (1) Improvement Activity 1 (IA-1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening and Improvement Activity 2 (IA-2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements (CCAs).

We did not receive any comments on our proposed general approach to evaluating ASM participants on the required improvement activities. Comments specific to the proposed improvement

activities are summarized and discussed below. Therefore, we are finalizing the provision related to evaluating ASM participants on the finalized improvement activities as proposed at § 512.735(b).

(i) Improvement Activity 1 (IA-1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening

In IA-1, we proposed at § 512.735(c)(1) to require annual attestations by ASM participants on activities related to enhancing connections to and relationships with primary care. As the first part of IA-1, we proposed at § 512.735(c)(1)(i) that ASM participants develop processes and workflows within their practices to identify patients without a PCP and assist them in finding one. Primary care is a vital resource for patients, providing an efficient and accessible level of care. We believe it is essential that the vast majority of patients have a PCP who can coordinate their overall health care needs, manage chronic conditions, and serve as the first point of contact for health concerns. However, some patients may not have a designated PCP, which can lead to fragmented care and suboptimal health outcomes. A 2022 study found that up to a third of Medicare beneficiaries do not see a PCP yearly.[268] Furthermore, we believe that connecting patients with a PCP could help reduce demand on specialists in situations where the patient could more appropriately be treated in the primary care setting. Continuity with a primary care practice or provider also has the potential to reduce costs.[269] We believe specialists can play a crucial role in ensuring that their patients have access to these high-value primary care services. As part of IA-1, we also proposed at § 512.735(c)(1)(ii) to require that the ASM participant always communicate relevant information back to the ASM beneficiary's PCP following the ASM beneficiary's visit with the ASM participant. This exchange of information is important to patient care planning and is an aspect of specialty care and primary care collaboration that has room for improvement.[270]

As the final element of IA-1, we proposed at § 512.735(c)(1)(iii) that ASM participants collaborate with PCPs to ensure that their patients have received health-related social needs (HRSN) screenings. In addition to ensuring access to primary care, we also recognize the importance of addressing patients' upstream drivers of health. These factors, such as housing, food insecurity, transportation, and

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[268] Barnett ML, Bitton A, Souza J, Landon BE. Trends in Outpatient Care for Medicare Beneficiaries and Implications for Primary Care, 2000 to 2019. *Annals of Internal Medicine*. Published online November 2, 2021. doi:*https://doi.org/10.7326/m21-1523*.

[269] Yang Z, Ganguli I, Davis C, et al. Physician- versus practice-level primary care continuity and association with outcomes in Medicare beneficiaries. *Health Services Research*. 2022;57(4):914-929. doi:*https://doi.org/10.1111/1475-6773.13999*.

[270] Timmins, Lori, et al. "Communication Gaps Persist between Primary Care and Specialist Physicians." *The Annals of Family Medicine*, vol. 20, no. 4, 1 July 2022, pp. 343–347, *www.annfammed.org/content/20/4/343, https://doi.org/10.1370/afm.2781*.

financial constraints, are common in the Medicare population. One study found that of approximately 68,000 Medicare Advantage patients who responded to a HRSN screening, 33 percent experienced financial strain, 18.5 percent experienced food insecurity, and 17.7 percent had poor housing quality.[271] These unmet needs can significantly impact a patient's well-being and contribute to the development or exacerbation of diseases, lead to unnecessary health care costs, and worsen overall outcomes.[272] HRSN screening also has the opportunity to open a dialogue between the patient and provider about lifestyle factors, such as diet and physical activity. This discussion with the provider and associated education can promote the adoption of a healthier lifestyle, thereby mitigating the presence of new or worsening diseases. Feedback from interested parties has indicated that PCPs are best equipped to conduct HRSN screenings and may have established relationships with community resources to address identified needs. While specialists may not have the resources to conduct HRSN screenings or be the most appropriate provider to address these concerns, we believe they should have some responsibility in ensuring HRSN screenings have been completed, considering unmet social needs can have a direct impact on the medical condition(s) they are managing. If a specialist identifies that a patient has not received an annual HRSN screening, they should communicate this information to the patient's PCP and encourage them to conduct the screening and initiate any necessary follow-up action(s). The specialist may also choose to conduct the screening themselves, as long as they communicate the results and any follow-up actions to the patient's PCP.

(ii) Improvement Activity 1 (IA-1) Specifications

IA-1 Name. Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening

IA-1 Specifications ASM participants must have evidence of processes, workflows, and/or technology that require the ASM participant to: (1) confirm the ASM beneficiary has access to primary care services and, if not, assist the ASM beneficiary in finding a clinician who provides primary care services, (2) communicate relevant information back to the ASM beneficiary's PCP following the ASM

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[271] Long CL, Franklin SM, Hagan AS, et al. Health-Related Social Needs Among Older Adults Enrolled In Medicare Advantage. *Health Affairs*. 2022;41(4):557-562. doi:*https://doi.org/10.1377/hlthaff.2021.01547.*

[272] ROI Calculator for Partnerships to Address the Social Determinants of Health Review of Evidence for Health-Related Social Needs Interventions. (2019). https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.

beneficiary's visit with the ASM participant, and (3) determine whether the ASM beneficiary has received an annual HRSN screening in the primary care setting and, if not, encourage the primary care services provider to conduct the screening or allow the ASM participant to conduct the HRSN screening. Evidence can include items such as the following:

- Documented workflows or protocols outlining the process for identifying patients without a designated PCP, assisting patients in finding and establishing care with a PCP (such as practice intake forms or integrated into normal practice in the patient's visit), sharing relevant information (test results, treatment plans, follow-up recommendations) with the patient's PCP after each visit, confirming if the patient has completed an annual HRSN screening, or conducting or communicating with the PCP to conduct an annual HRSN screening if it has not been done.
- EHR system configurations or templates, or other health IT tools, that facilitate capturing and documenting the patient's PCP information, generating and sending visit summaries or reports to the PCP, or recording HRSN screening status and prompting follow-up actions.
- Staff training materials or competency assessments related to identifying patients without a PCP and assisting them in finding one, proper documentation and communication of information to the PCP, or inquiring about HRSN screening status and initiating appropriate follow-up.
- Audit trails or reports from the EHR or practice management system demonstrating patients who were identified as not having a PCP and the actions taken, visit summaries or reports sent to the PCP after each patient encounter, or patients who were confirmed to have completed an annual HRSN screening or underwent one or were referred to the PCP for one.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed IA-1, noting that enhanced coordination between specialists and PCPs is critical for effective cardiovascular care and improving care coordination.

Response: We appreciate the support for IA-1 and believe the implementation of this improvement activity will bring valuable insights and impact of HRSN screening in specialty care settings. We agree that coordination between primary and specialty care is essential for achieving

comprehensive patient care and addressing upstream drivers of health that significantly influence chronic disease management and outcomes.

Comment: A few commenters supported the proposed IA-1: Connecting to Primary Care and offered additional recommendations. A commenter suggested CMS consider a multidisciplinary, system-level approach rather than holding the ASM participant responsible for the activity at the individual level. Another commenter shared their belief that some practices may not have the data infrastructure to handle IA-1, which would unfairly penalize clinicians. Another commenter shared their belief that the proposed IA-1 focuses more on the process rather than the outcomes, which could add administrative burden leading to clinician burnout. A commenter suggested CMS to simplify the IA-1 by: developing additional quality measures for specialists to demonstrate collaboration with primary care, requiring specialists to meet a threshold percentage for having a PCP listed, confirming whether the HRSN screening or an annual wellness visit was completed, or assisting patients in finding a PCP that can perform the screening.

Response: We appreciate commenters for their support and recommendations regarding the proposed IA-1: Connecting to Primary Care. We have adjusted the data submission requirements of ASM at § 512.720(a)(1)(ii) to allow for the Improvement Activities to be reported at the TIN level, in order to promote team-based care and coordination as the requirements of this ASM performance category typically reflect work done at the practice level. We believe that changing this reporting level from the individual clinician to the TIN level decreases administrative burden while still maintaining accountability for these important care coordination activities. We intend to provide participants with additional resources on model requirements and performance category requirements in the year leading up the model start. We intend to make these resources available on the ASM website. While we appreciate the comment to create a quality measure for this activity to assess coordination and collaboration, that is not feasible at this time and would present an additional burden to ASM participants. We also believe that the annual attestation of this activity is low burden as it does not require ongoing submission of detailed data.

Comment: A few commenters did not support the IA-1: Connecting to Primary Care, noting concerns around the need for manual data when electronic health records (EHR) or Health Information Exchange (HIE) are not shared between practices, lack of interoperability for social determinants of

health (SDOH) data, absence of closed-loop referral tracking and misalignment of financing. A commenter specifically called out anesthesiologists as being the inappropriate care team member to identify a PCP due to their limited interactions with patients during episodic care. The commenter recommended that CMS propose an improvement activity that better reflects the expected roles and workflows of anesthesiologists.

Response: We appreciate the feedback about IA-1. While there may be effort associated with implementing IA-1: Connecting to Primary Care, we believe the activities proposed in IA-1 are vital to patient care and reducing care fragmentation, and many of these coordination activities should already be occurring as part of comprehensive patient management. The preliminary participant list for CY2027 will be posted in early 2026, nearly a year in advance of the model start. This will provide ASM participants with nearly a year in advance to prepare their HIE systems and adjust to some of these activities, such as HRSN screening checks.

The ASM participant themself does not need to directly connect the patient to a PCP. It can be a separate activity not tied to the HIE system and/or an initiative/process within their practice or health system to ensure this coordination is happening effectively. Also, even though anesthesiologists may have limited interactions with patients during episodic care, we believe anesthesiologists should still be ensuring their patients are receiving longitudinal care coordination and help connect them to a PCP when needed. Furthermore, we believe our methodology for participant inclusion in ASM is focused on providers that have been attributed at least 20 patients with the condition of interest, which will identify clinicians that are more likely to have ongoing relationships with patients. This makes it more reasonable to expect these care coordination activities from these anesthesiologists who are ASM participants.

Comment: A few commenters expressed general concerns regarding the proposed IA-1: Connecting to Primary Care. A commenter expressed concern that the model may be less effective for primary care practices due to the lack of direct funding for PCPs, who are already overburdened. A commenter recommended that CMS offer technical assistance and upfront funding to PCPs. Another commenter suggested that CMS should provide additional resources for investments to support coordination.

Response: We appreciate the feedback regarding concerns about the effectiveness of IA-1: Connecting to Primary Care for primary care practices and the need for additional support resources. We understand the challenges facing PCPs and recognize the importance of supporting their participation in care coordination activities. Codes for e-consults and interprofessional communication already exist for ASM participants and PCPs to receive reimbursement for their collaborative efforts. Furthermore, we believe these coordination efforts will reduce care fragmentation and improve efficiency, which may provide financial benefits to ASM participants and the primary care practices with whom they partner through reduced duplicative services, improved patient outcomes, and more streamlined care delivery. The improved coordination should also lead to better patient satisfaction and potentially reduced administrative burden over time as communication pathways become more established. We recognize that successful implementation of this improvement activity requires adequate support for both specialists and PCPs. We intend to provide participants with additional resources and support on model requirements and performance category requirements in the year leading up the model start. We intend to make these resources available on the ASM website.

Comment: Several commenters provided recommendations for IA-1. One commenter recommended a more holistic approach to screening that included connecting patients to resources and offering community solutions.

Response: The primary goal of IA-1 is to ensure comprehensive care coordination and HRSNs that significantly impact outcomes for beneficiaries with these chronic conditions. We appreciate the commenter's support for our HRSN screening efforts and the observation that screening alone does not connect patients to resources. We believe that incentivizing screening is the essential first step to connecting patients to these resources. As ASM operates at the specialist level, there are minimal direct levers for the model to connect patients to community resources, but the screening and coordination requirements create pathways for PCPs and care teams to facilitate these connections.

Comment: Several comments provided recommendations about IA-1. One commenter suggested that longitudinal models that engage specialists over the course of chronic care conditions such as through condition-based or per-person payments would allow for team based care, collaborations, and

interventions. Another commenter stated their belief that FFS payment models do not account for the time and effort needed to implement screening and refer patients.

Response: We appreciate the supportive feedback and thoughtful recommendations regarding IA-1. Our model is for low back pain and heart failure, two chronic diseases in which HRSN screening and collaboration can greatly improve care and reduce fragmentation for the patient. We agree that longitudinal care models are important, but this is not the sole goal of ASM. We are targeting specific conditions for improvement and believe that within the larger context of the healthcare ecosystem, ACOs and other value-based care systems will be supported. By promoting this connection between providers, we are enforcing longitudinal relationships and care continuity for patients with heart failure and low back pain. Furthermore, we believe that the payment structure of the model incentivizes these efforts and rewards them more than the traditional FFS system. ASM promotes coordination, HRSN screening, and quality improvement efforts by measuring them and providing potential positive payment adjustments for those participants achieving these desired goals.

Comment: Several commenters provided feedback on IA-1 related to interoperability. A commenter also recommended that CMS define the expectations now and measure them later and align the model to the HL7 Gravity FHIR Implementation Guide for data transfer and timeline should be coordinated with Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health IT (ASTP/ONC) certification and vendor upgrades. Another commenter noted that CMS should phase in expectations aligned with national standards such as Gravity, CCA templates, and finance operations.

Response: We appreciate the comments. We recognize the importance of aligning with national standards such as the Gravity Project to promote interoperability and reduce implementation burden. We will also explore opportunities in the future to align with these efforts and others that will support effective implementation. Also, we are interested in providing resources and materials to support the improvement activities performance category and other model requirements. We intend to make these resources available on the model website.

Comment: A few commenters stated this proposal will add burden to specialists. One commenter noted the time this will take during already packed office visits, workflow changes, interoperability

concerns, and buy-in from clinicians with other employers who are not ASM participants. The commenter recommended that CMS codify "screen once, share widely" to prevent duplication and that compliance be achievable through EHR rather than separate portals or manual lookups. Another commenter suggested simplifying the HRSN policy, because it could lead to finger pointing between specialists and PCPs. A commenter stated their belief that infrastructure, workflow standards, and financing will drive duplicative screening and increased the administrative burden.

Response: We appreciate the commenters' feedback. We understand the concerns about infrastructure, workflow standards, and buy-in. We believe that the advanced notification of mandatory participation as described in section III.C.2.c.(5) of this final rule would provide ASM participants with time to prepare for the model requirements, such as developing workflows and partnerships that support effective HRSN screening and care coordination. We also intend to release additional guidance and resources before the model launches in CY 2027. The model's emphasis on communication and care coordination should ultimately reduce fragmentation and improve efficiency for both specialists and PCPs while ensuring that patients receive comprehensive care that addresses both their clinical conditions and HRSNs. Regarding concerns about duplication and the need to codify "screen once, share widely," we believe the current IA-1 policy is effective because it promotes coordination between specialists and PCPs while addressing HRSN screening for beneficiaries with heart failure and low back pain. The existing policy already encourages the "screen once, share widely" principle by allowing specialists to satisfy requirements when they can access valid existing screening results through established communication channels and HIEs. Also, while there is a chance that minor duplication of HRSN screening may occur between specialists and PCP, we believe this can be mitigated by proper communication process and that it is a reasonable trade-off to ensure that patients are receiving appropriate screening and being connected to the resources they need to maintain their health. The primary goal of IA-1 is to ensure comprehensive care coordination and address social determinants of health that significantly impact outcomes for beneficiaries with these chronic conditions.

Comment: A commenter expressed their belief that misalignment between programs increases administrative complexity, including workflow changes and data infrastructure investments, as seen in the proposed removal of HRSN from the MIPS Quality and Improvement Activities categories and the

inclusion of IA-1 in ASM. A commenter stated it was contradictory to include HRSN screening in ASM but remove SDOH screenings. A commenter recommended CMS review proposed SDOH changes across programs for consistency.

Response: We appreciate the commenter's feedback. ASM is a distinct model separate from other payment programs. While we strive to align where possible, differing approaches may persist. HRSN screening is especially important in patients who have heart failure and low back pain and may be at greater risk, and therefore greater benefit, from screening and intervention. For this reason, we will include HRSN screening in ASM and continue aligning with other payment programs where possible.

Comment: A commenter recommended CMS collect and disseminate HRSN information since they are better positioned and the HRSN screening falls outside of heart failure and low back pain specialists' clinical scope.

Response: We appreciate the feedback regarding the dissemination of HRSN information. We believe that ensuring HRSN screening has occurred is important when dealing with patients with the ASM chronic conditions of focus, and therefore, it is within scope. We plan to provide as much relevant information and data to participants in advance of and during the model. This may not explicitly include HRSN screening data, but other information that we believe will be beneficial to ASM participants.

Comment: A commenter expressed their belief that some patients may not have a PCP and that physicians may not share their HRSN information. A commenter expressed their concern about the role of the specialist ensuring the PCP completes the screen and the potential of the patient being unwilling to see a PCP. A commenter expressed their belief that there should be clear exceptions for specialists if a patient declines a PCP, lives in a primary care shortage area, or the primary care physician declines the screening.

Response: We appreciate the comments around the roles of the specialist and PCP in HRSN screening. We support the connection of patients to care but recognize that this is not always the primary role of the specialist, so we have specified that the specialist should ensure the HRSN screening is completed by the PCP, or by them if needed, and believe that the proper next steps will occur through this coordination. We appreciate the comment around clear exceptions in cases where patients decline PCP connections, live in primary care shortage areas, or when primary care physicians decline to participate in screening activities. The improvement activity requires that there are processes, workflows, or technology

in place to connect all patients to a PCP and HRSN screening. We want to incentivize as much action toward achieving these ASM goals as possible, acknowledging that there may be specialists who are well positioned to help identify a PCP for the patient when a PCP is difficult for the patient to find themself.

Comment: A few commenters recommended that CMS should advise which HRSN screening tools are acceptable so vendors can integrate these tools into clinical workflows.

Response: We appreciate the request to advise on screening tools. We do not specify a particular HRSN screening tool to allow flexibility for participants to choose tools that work best with their existing workflows and EHR systems. We may provide additional guidance in the future to support decision-making. Also, we note that the IA-1 does not require that the HRSN screening be conducted by the specialist, unless it is unable to be completed by the PCP, acknowledging that PCPs may have more experience with HRSN screenings and connecting patients to resources, if needed.

Comment: A commenter recommended that specialists receive full credit for sending EHR documentation and visit summary to a primary care physician within a defined timeframe.

Response: Participants have flexibility to integrate the IA-1 requirements however they choose whether through manual processes or automated systems as part of their EHR or other health information technology platforms. The situation described by the commenter would meet the expectations for communicating relevant information back to the ASM beneficiary's PCP, which is one part of IA-1. This communication between specialists and PCPs should help minimize duplication of HRSN screening when existing results can be accessed and shared effectively through established workflows and HIE.

After consideration of public comments, we are finalizing IA-1 and its specifications as proposed at § 512.735(c)(1).

(iii) Improvement Activity 2 (IA-2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements (CCAs)

In IA-2, we proposed at § 512.735(c)(2) to require annual attestations by ASM participants on activities related to establishing collaboration expectations with primary care. We believe that formalizing the collaborative relationship between ASM participants and PCPs through a collaborative care arrangement (CCA) is an important step to reduce patient fragmentation of care and ensures vital coordination activities are occurring. As discussed further below, we proposed defining "collaborative

care arrangement" to mean an arrangement that complies with all of the requirements set forth in § 512.771. We also proposed to define "ASM beneficiary" at § 512.705 as a Medicare FFS beneficiary who is being treated by an ASM participant for a targeted chronic condition. There are several possible aspects to a CCA, but the goal of the CCA is to set forth expectations between the parties to facilitate primary care and specialty care integration for the benefit of the patient while ensuring both parties are held accountable for how they fulfill their duties.

We sought comments on our proposed definition for "ASM beneficiary". We did not receive specific comments on our proposed definition of "improvement activities," so we are finalizing it as proposed at § 512.705.

To receive achievement points for IA-2, we proposed at §§ 512.735(c)(2)(i) and (ii) that the ASM participant must enter into at least one CCA with a primary care practice that includes at least three of the following five following collaborative elements: data sharing, co-management, transitions in care planning, closed-loop connections, and care coordination integration as proposed at §§ 512.735(c)(2)(ii)(A) through (E). All of these CCA elements support an important prevention framework by promoting a seamless information ecosystem where providers collaborate to detect health risks before they occur and optimize care through communication. These elements also have properties that may overlap in their implementation with each other and IA-1, which together further the goals of the improvement activities ASM performance category.

The sharing of data back to PCPs is crucial for ensuring continuity of care for shared patients. Specialists should have clear processes in place to provide timely updates, test results, treatment plans, and follow-up recommendations to the patient's PCP, even outside the time of a referral between the parties. We also believe this exchange should be bi-directional, so that both entities have a comprehensive understanding of the patient's condition and can provide appropriate follow-up care and management.

Co-management is a collaborative approach where specialists and PCPs work together to provide coordinated care for patients with complex or chronic conditions. Generally, the different types of co-management include consultative co-management, where the specialist provides consultation and recommendations to the PCP who remains the primary manager of the patient's care; shared co-management, where both the specialist and PCP actively participate in managing the patient's care with

clearly defined roles and responsibilities; and principal co-management, where the specialist takes the lead in managing the patient's condition while the PCP provides overall coordination and management of other aspects of the patient's care.[273] The benefits of co-management include shared decision-making and treatment planning, consistent monitoring and follow-up of the patient's condition, reduced duplication of tests and procedures, enhanced patient education and self-management support, and better management of comorbidities and potential drug interactions. Additionally, we believe co-management can lead to better health outcomes, improved patient satisfaction, and potentially lower health care costs by reducing fragmentation and unnecessary utilization of health care resources.

Transition in care planning refers to the processes and protocols in place for seamlessly transitioning a patient's care between specialists and PCPs, or between different care settings (for example, hospital to outpatient care).[274] Care planning can include follow-up appointments, medication reconciliation, and clear communication of the treatment plan. We believe effective transitions in care planning can help prevent gaps in care, reduce hospital readmissions, and ensure continuity of care for the patient. It may also involve defining roles and responsibilities for coordinating care, conducting warm handoffs, and ensuring timely follow-up appointments. When meaningfully implemented, it promotes a seamless and coordinated approach to care, where all providers involved have a shared understanding of the patient's needs and can work together to provide high-quality, patient-centered care.

Closed-loop communication and feedback between specialists and PCPs involve establishing a structured and coordinated process for when the patient is referred from primary care to specialty care and back. The model considers this to include elements such as structured referral templates, communication and information sharing, collaborative treatment planning, and shared monitoring of patient outcomes. By coordinating care effectively, providers can identify and address potential issues or gaps in care, reduce duplication of services or tests, and ensure that patients receive appropriate and timely care, ultimately improving quality and preventing unnecessary utilization of health care resources.[275]

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[273] Kuo D, Gifford DR, Stein MD. A typology of specialists' clinical roles. Arch Intern Med. 2009;169(11):1062-1068. doi:10.1001/archinternmed.2009.114.
[274] Smith, Lucia Rojas, et al. *Care Transitions Framework*. *Www.ncbi.nlm.nih.gov*, Agency for Healthcare Research and Quality (US), 1 Mar. 2014, *www.ncbi.nlm.nih.gov/books/NBK196206/*.
[275] Murray M. Reducing Waits and Delays in the Referral Process. *Family Practice Management*. 2002;9(3):39-42. https://www.aafp.org/pubs/fpm/issues/2002/0300/p39.html.

Care coordination activities generally refer to efforts by the ASM participant to identify areas of their practice that could be improved by codified workflows or initiatives, as well as establishment of these activities collaboratively with the partnered primary care practice. These innovations support an environment of continuous improvement for practices and positive outcomes for their shared patients.

When selecting primary care practices for CCAs, ASM participants must ensure the CCA is with a primary care practice with whom they share at least one ASM beneficiary. We recommend that the ASM participant explore entering into a CCA with a primary care practice with whom the ASM participant shares a meaningful portion of their Medicare patients, to maximize the impact of the CCA activities. That is, ASM participants should seek to enter into a CCA with another primary care practice with which they share the largest number of ASM beneficiaries. If that is not feasible, then ASM participants should seek to enter into a CCA with a different primary care practice that they share a significant portion of ASM beneficiaries with.

(iv) Improvement Activity 2 (IA-2) Specifications

IA-2 Name. Establishing Communication and Collaboration Expectations with Primary Care Practices using Collaborative Care Arrangements (CCAs)

IA-2 Specifications. Documentation of at least one executed CCA between a primary care practice with which the ASM participant shares ASM beneficiaries, and the CCA must include collaborative efforts related to at least three of the following five elements:

- *Data Sharing*. Setting expectations for bi-directional sharing of patient information between the parties to the CCA, including but not limited to test results, treatment plans, and follow-up recommendations. This is aimed toward population health management of shared patients and is not necessarily coordinated around a specific referral episode. Elements may include: (1) evidence that the ASM participant always sends a report to the referring PCP; or (2) a process for capturing referral information that the ASM participant has a defined method for capturing reports from the PCP in the medical record, for example: reports transmitted between EHRs; documents that are electronically scanned and linked to the patient's EHR; or chart documentation of the relevant details of the specialist-patient interaction, such as notes written into a progress note.

- *Co-Management*. Criteria that define co-management approaches, where the parties to the CCA work together to furnish complementary care for patients with complex or chronic conditions. The criteria should clearly set forth the available co-management approaches. Examples of such co-management relationships may include: (1) consultative co-management, (2) shared co-management, or (3) principal co-management.

- *Transitions in Care*. Defined protocols for seamless transitions of care between ASM participants, the primary care practice, or different care settings. Elements may include: (1) patient-centered care transition action plans, such as documented plans from the ASM participant to the PCP, including outpatient follow-up recommendations, medication reconciliation, and any necessary post-transition support; (2) implementation of the transition plan, including documentation of staff involved in the care transition, records of real-time communication between the ASM participant and the primary care practice, and ensuring the primary care practice is included in any follow-up transition communication; or (3) care transition planning processes, which outline steps the ASM participant would take to prepare and implement the patient-centered care transition plan when transferring care to the PCP.

- *Closed-Loop Communication*. Clearly articulated processes enforcing parameters on how ASM beneficiaries may be referred between the parties to an executed CCA. These structured and enhanced referral processes would add efficiency to communications between the parties to the CCA and ensure expectations around what is needed for effective specialty consultation and collaboration. Examples of provisions that should be included are as follows: (1) expectations for the structure, elements, and flow of information and responsibilities between practices during a referral; (2) monitoring of shared ASM beneficiaries through the entire process to ensure proper follow-up, integration of information, and maintenance of beneficiary choice; and (3) integration of information from the closed-loop connection into the ASM beneficiary's plan of care.

- *Care Coordination Integration*. Structured processes to embed care coordination processes into the ASM participant's practice workflow. Such processes may include: (1) activity records documenting the implementation of care coordination activities with the primary care practice, such as meeting minutes on process improvements, workflow diagrams, training syllabi for training staff on new

processes, copies of old and new processes on documenting care coordination activities; or (2) outcome measures demonstrating changes attributable to newly implemented care coordination processes.

We solicited comments on the goals and specifications of the required improvement activities proposed at § 512.735(c)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed Improvement Activity 2 (IA-2) requiring ASM participants to enter a CCA with PCPs with three of the five following areas including data sharing, co-management, transitions in care planning, closed loop connections and care coordination integration and offered further recommendations. A commenter recommended that CMS take a similar approach to the Making Care Primary (MCP) program by implementing specific coding and payment for consultations, noting that incentivizing collaboration is more likely to have a meaningful impact. Another commenter recommended that CMS align ASM care coordination requirements with existing Chronic Care Management (CCM)/ Advanced Primary Care Management (APCM) frameworks to reduce reporting burden.

Response: We appreciate the support of IA-2. We do not believe model specific payment codes would add value or align with the goals of ASM. We believe the improvement activities framework adequately supports the goals that these codes would accomplish. ASM participants and their partnered PCPs will more often be collaborating and coordinating care, providing more opportunities for them to appropriately bill the existing CCM, APCM, IPC, and e-consult codes. We will continue to think about how we can communicate the use of these existing codes and their alignment with our improvement activities goals in future guidance. Finally, we believe these coordination efforts required by ASM will reduce fragmentation and improve efficiency, which may provide financial benefits to participants and partnered primary care practices alike.

Comment: A commenter recommended CMS permit specialists to partner with third-party care management companies to meet coordination requirements and ensure access to infrastructure. Another commenter recommended that CMS publish clear requirements for CCAs, including requiring specialists and PCPs to have detailed operational plans and coordination activities. Another commenter

recommended requiring specialists to share a copy of the CCA to provide insights into how market participants operationalize collaborative elements.

Response: We appreciate the feedback regarding partnerships with third-party care management companies and the development of CCAs for ASM. If a high-value third party can support coordination efforts, an ASM participant may work with them to achieve the improvement activity requirements.

We would be interested in participant feedback as they implement these coordination activities. However, we are not requiring the submission of CCAs as we are concerned with creating an excess administrative burden for ASM participants. We believe that the annual attestation approach strikes the appropriate balance between ensuring accountability for coordination activities and minimizing reporting burden. This approach allows participants the flexibility to develop coordination strategies that work best for their specific practice environments while still maintaining oversight of these important activities.

Comment: A few commenters supported the proposed IA-2. The commenters acknowledged the importance of incentives for promoting coordination between primary care physicians and specialists.

Response: We appreciate commenters' supportive feedback regarding the proposed IA-2. We agree with commenters about the importance of incentives for promoting coordination between primary care physicians and specialists. We believe that establishing clear collaboration expectations through annual attestations will help strengthen the care coordination framework that is essential to the success of ASM. We believe success in ASM and potential positive payment adjustments is the incentive.

Comment: Several commenters did not support IA-2. A commenter shared their belief that specialists should not be required to have any type of coordination arrangements with primary care physicians. Another commenter expressed concern that the CCAs were overly burdensome, particularly for clinicians outside of a larger system who lack the staff to manage such arrangements. Another commenter shared their concerns that 6 months is insufficient for providers to establish care coordination processes, and that the policy imposes significant workflow adjustments and administrative burdens within a short timeframe. A commenter expressed concern that ASM participants are at a disadvantage in negotiating CCAs, as PCPs are not required to participate. A few commenters expressed concern that it would be burdensome for ASM participants to enter into multiple CCAs given the range of patient primary care services. Another commenter noted that, despite having EHRs, reliance on fax persists due

to external clinician systems, and the proposed improvement activity depends on cooperation from unaffiliated clinicians. Another commenter recommended granting credit for the improvement activity if clinicians share a common EHR or HIE.

Response: We appreciate the feedback regarding Improvement Activity (IA) 2. We are purposefully requiring specialists to engage with PCPs as a core goal of the model is to reduce fragmentation for patients and improve care collaboration. We believe an appropriate mechanism to achieve this is through CCAs.

We recognize the effort this requirement may take but intend to provide additional resources to support practices and believe that in the long term, the coordination that IA-2 promotes may create efficiency through streamlined interactions with PCPs in situations of co-management or referral optimization. Also, for the CY 2027 performance year, we intend to release the preliminarily eligible list of participants in early CY 2026. This provides nearly a year of advance for ASM participants to prepare for IA-2. Further, IA-s only need to be implemented for a portion of the performance year in order to attest to the activity, providing additional time for the participant to meet the requirements.

We believe that primary care practices will be interested in engaging in CCAs as they also benefit them by building and strengthening relationships that can improve care coordination. We do not require the participant to enter into multiple CCAs, only one. Identifying a PCP with whom the ASM participants has the most shared patients could maximize the impact of the CCA.

We believe this coordination requirement is necessary to promote the collaboration we aim to achieve in ASM. Additionally, IA-2 does not specify that the primary care partner must be external. If an ASM participant is in a multi-specialty system, the participant may develop a CCA with a primary care group within that system. In this way, there is the opportunity to minimize additional complications related to external CCAs, if the other expectations of the CCA are met.

Regarding concerns about EHR interoperability and reliance on external systems, we acknowledge these challenges but believe we allow enough flexibility in IA-2 for ASM participants to explore multiple avenues to address them. If participants share an EHR, the benefit would be the minimal effort involved in achieving improvement activity requirements.

Comment: A few commenters supported the proposed IA_2 but shared additional

recommendations. A commenter shared their belief that specialists should not be penalized for primary care actions and credit should only be applied to the actions within the specialist's control. Another commenter recommended that CMS further clarify the operational details of the five proposed collaborative elements to avoid a check-the-box approach.

Response: We appreciate the commenters for the supportive feedback regarding the proposed IA-2. The improvement activity focuses on the specialist's role in establishing and maintaining collaborative relationships and communication pathways with PCPs, rather than holding them accountable for PCP actions or decisions. Regarding the recommendation to clarify operational details of the five proposed collaborative elements, we appreciate this feedback and intend to provide additional resources to clarify details of CCAs in advance of the model start. Our goal is to ensure that these improvement activities promote meaningful collaboration rather than a check-the-box approach, and we will work to provide guidance that helps participants understand how to operationalize these coordination requirements in ways that genuinely improve patient care and reduce fragmentation.

Comment: A commenter recommended that ASM improvement activities be approved as improvement activities in traditional MIPS for the CY 2026 performance period to allow time for likely ASM participants to prepare.

Response We appreciate the feedback regarding the alignment of ASM improvement activities with MIPS. We will take the comment into consideration for future coordination with MIPS. We note that there is overlap between the requirements of the MIPS IAs in the Care Coordination section and the ASM IAs.

After consideration of public comments, we are finalizing our definition of "collaborative care arrangement" without modification at § 512.705. We are also finalizing IA-2 and its specifications as proposed at § 512.735(c)(2).

(d) Improvement Activities Data Submission, Achievement Points, ASM Performance Category Scoring

We proposed that ASM participants must submit data on ASM improvement activities in the form of attestations meeting the submission requirements at § 512.720. We proposed at § 512.735(d)(1) and (2) that ASM participants would receive 10 measure achievement points for reporting "yes" for each improvement activity specified at § 512.735(c) in accordance with the data submission requirements at §

512.720(a). We would sum the total achievement points for all submitted improvement activities and divide this sum by the total number of available achievement points for the required improvement activities as specified in paragraph § 512.735(c), not to exceed 100 percent.

In our proposals, both improvement activities would be weighted the same, each accounting for half of the potential improvement activities ASM performance category scoring adjustments to the final score. We considered differential weighting, with IA-1 comprising a smaller number of points for the scoring adjustment. The activities in IA-1, such as sharing patient information back to a PCP after a specialist visit, should already be occurring, whereas activities in IA-2, like the creation of a CCA, are less common and potentially more time consuming. We decided to propose to weight the improvement activities equally, each accounting for the same number of potential points in the improvement activities ASM performance category scoring adjustment, acknowledging the burden that these improvement activities may present to practices. For example, if an ASM participant is already conducting activities that satisfy IA-1 specifications but do not satisfy IA-2 specifications in the 2027 ASM performance year, they would still be awarded 10 measure achievement points and an improvement activities ASM performance category score of 50 percent. We believe IA-1 would be achieved by the vast majority of ASM participants with limited effort, which may lessen the concern of initial improvement activity burden and impact to the ASM participant's overall score. Simultaneously, we want to promote specialty collaboration with primary care, thus if ASM participants do not achieve the expectations in IA-2, the ASM participant would only receive 10 measure achievement points. If ASM participants do not complete the requirements for IA-1 and do not complete the requirements for IA-2, they will receive zero measure achievement points and an improvement activities ASM performance category score of zero percent.

We solicited comments on our improvement activities ASM performance category scoring approach at § 512.735(d)(1) and (2) and alternative improvement activities weighting and scoring options. We did not receive public comments on this provision, and therefore, we are finalizing as proposed at § 512.735(d).

(5) Promoting Interoperability ASM Performance Category

Our long-term goal for the Promoting Interoperability performance category is to ensure the meaningful use of CEHRT and information exchange throughout the year for all data, clinicians, and patients. We believe it is important to leverage the Promoting Interoperability ASM performance category for scoring adjustments to the final score, as discussed in section III.C.2.e. of this final rule.

(a) Background

In the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we included proposals for defining the performance year for Promoting Interoperability measures, the requirement for CEHRT use and related attestations, and data submission criteria and scoring for the ASM Promoting Interoperability performance category. As discussed in section III.C.2.e. of this final rule, the Promoting Interoperability ASM performance category score will be used to determine the Promoting Interoperability ASM performance category scoring adjustment applied to the final score.

(b) ASM Performance Year for the Promoting Interoperability ASM Performance Category

At § 512.740(a), we proposed the ASM performance year for Promoting Interoperability ASM performance category. Beginning with ASM payment year 2029, the performance year for Promoting Interoperability measures will be a minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

As discussed in the CY 2026 PFS proposed rule (90 FR 32593), this reporting period aligns with the MIPS performance period established at § 414.1320(i)(1) and provides ASM participants adequate opportunity to monitor and submit performance data. We believe that alignment of the performance period between MIPS and ASM helps support the transition of ASM participants from MIPS to ASM and reduce administrative burden for clinicians who are familiar with reporting in the existing MIPS performance period.

We solicited comments on our proposal at § 512.740(a) for the 180-day performance period for Promoting Interoperability measures. The following is a summary of the comments we received on defining the Promoting Interoperability ASM performance year and our responses.

Comment: A few commenters supported the proposal to use a continuous 180-day period within the calendar year as the performance year for the Promoting Interoperability ASM performance category, noting alignment with MIPS and the Medicare Promoting Interoperability programs. The commenters

shared this approach would reduce administrative burden for clinicians who are already familiar with these reporting timelines and processes and would allow leveraging existing infrastructure.

Response: We appreciate the commenters for their support of using a continuous 180-day period during the calendar year as the performance year for the Promoting Interoperability ASM performance category.

Comment: A commenter recommended CMS not to extend the ASM Promoting Interoperability performance year beyond 180-days in a future rule, expressing concern that a longer reporting period could create challenges to electronic health records (EHR) vendors who require adequate time for software updates, user training, and testing while supporting multiple facilities.

Response: We want to clarify that we did not propose to extend the ASM Promoting Interoperability performance period beyond 180-days. We appreciate the commenter for the suggestion and will consider it in the future should we decide to make changes to the proposed definition being finalized at § 512.740(a).

After consideration of public comments, we are finalizing this proposed definition of the ASM Promoting Interoperability performance year at § 512.740(a).

(c) Reporting for the Promoting Interoperability Performance Category

We proposed at § 512.740(b) to earn a performance category score for the Promoting Interoperability ASM performance category for inclusion in the final score, an ASM participant must be a meaningful EHR user meeting certain criteria. In the CY 2026 PFS proposed rule (90 FR 32593), we proposed to define "meaningful EHR user" at § 512.705 to mean an ASM participant who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability ASM performance category for a performance period in the form and manner specified by CMS, and engages in activities related to supporting clinicians with the performance of CEHRT. We proposed to not include additional provisions related to information blocking as defined at 45 CFR 171.103 in the definition of a meaningful EHR user. In addition, the Promoting Interoperability ASM performance category will focus on the safe use and exchange of patient data. Our requirements to demonstrate meaningful CEHRT use through reporting Promoting Interoperability objectives and measures are discussed later in this section of this final rule at III.C.2.d.(5)(c)(ii).

(i) Required CEHRT Use

We proposed our requirement for CEHRT use at § 512.740(b)(1) that ASM participants are required to provide evidence, in a form and manner specified by CMS, demonstrating their use of CEHRT to fulfill the Promoting Interoperability measure requirements (as defined at § 414.1305) and receive a score greater than zero percentage points for the Promoting Interoperability ASM performance category. ASM participants must use certified health IT that meets the definition of CEHRT at § 414.1305 (which references health IT certification criteria finalized at 45 CFR 170.315) to receive a score greater than zero for the Promoting Interoperability ASM performance category. To demonstrate evidence of CEHRT use, ASM participants would be required to provide their EHR's CMS identification ID from the Certified Health IT Product List, available on *HealthIT.gov*.

As discussed in the CY 2026 PFS proposed rule (90 FR 32593 through 32594), we believe requiring the use of CEHRT supports the goals of ASM by helping enable: (1) meaningful EHR use, further measured by ASM's proposed Promoting Interoperability objectives and measures; (2) reporting of clinical quality measures, including eCQMs; (3) interoperability and data sharing between clinicians and with patients to drive better patient care, care coordination, and primary and specialty care integration; and (4) continuous practice-based quality improvement and care transformation. To promote standardization, we proposed to align with the definition of CEHRT at § 414.1305 used across CMS in other Promoting Interoperability and quality reporting programs. For example, CEHRT use is required for eligible clinicians participating in the MIPS program as stated at § 414.1375(b)(1).

In addition to requiring use of CEHRT, we also proposed (90 FR 32593 through 32594) maintaining the requirement ASM participants submit confirmation of the following to earn a score for this category:

- The Office of the National Coordinator for Health Information Technology (ONC) direct review attestation at 45 part 170, subpart E.
- The Security Risk Assessment Measure.
- The High Priority Practices Guide of the Safety Assurance Factors for EHR Resilience (SAFER) Guides[276] Measure.

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[276] https://www.healthit.gov/topic/safety/safer-guides.

We proposed (90 FR 32593 through 32594) to not include the Actions to Limit or Restrict Compatibility or Interoperability of CEHRT attestation in ASM currently required under MIPS at 42 CFR 414.1375(b)(3)(iii).

As discussed in the CY 2026 PFS proposed rule (90 FR 32593 through 32594), we believe maintaining the ONC direct review process (45 CFR part 170, subpart E) in ASM increases accountability among certified health IT developers and vendors by ensuring ASM participants' Health IT Module[277] conforms to ONC Health IT Certification Program's requirements not only during implementation of CEHRT, but also while CEHRT is being used during patient care and in care delivery. In addition, we proposed at § 512.740(b)(3)(ii) that an ASM participant must complete the activities included in the Security Risk Analysis measure within the calendar year of the ASM performance year. As discussed in the CY 2026 PFS proposed rule (90 FR 32594), this aligns with a MIPS requirement for eligible clinicians in MIPS as stated at § 414.1375(b)(2)(ii)(A); we anticipated ASM participants that previously participated in MIPS would likely be familiar with these requirements. The security risk analysis is conducted to protect the security of individually identifiable health information and the systems that are used to create, receive, maintain, or transmit such information. An ASM participant would conduct a security risk analysis[278] in accordance with 45 CFR 164.308(a)(1)(A). As part of the security risk analysis, ASM participants will be required to address the security of electronic protected health information (ePHI) created, received, maintained, or transmitted by CEHRT, including whether it will be reasonable and appropriate in the participants' specific circumstances to encrypt ePHI in their CEHRT in accordance with requirements in 45 CFR 164.306(d)(3) and 45 CFR 164.312(a)(2)(iv), implement security updates as necessary, and correct identified security deficiencies as part of the ASM participant's risk management process.

We also proposed at § 512.740(b)(3)(iii) that the ASM participant must confirm the ASM participant's completion of the annual self-assessment under the High Priority Practices Guide of the SAFER Guides measure within the calendar year of the ASM performance year. As discussed in the CY

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[277] 45 CFR 170.102.

[278] Security Risk Analysis: https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2025-MIPS-Promoting%20Interoperability-Measure-Security-Risk-Analysis.pdf.

2026 PFS proposed rule (90 FR 32594), the High Priority Practices Guide of the SAFER Guides measure[279] is an annual self-assessment to support consistent safety practices for all EHR users, which helps enable the electronic exchange of health information and aligns with a requirement for eligible clinicians in MIPS as stated at § 414.1375(b)(2)(ii)(D).

As discussed in the CY 2026 PFS proposed rule (90 FR 32594), we believe these measures drive more secure, efficient, and meaningful use of CEHRT and health IT in ASM. Furthermore, given current and historical requirements in the Promoting Interoperability performance category in MIPS, these requirements are likely familiar and already implemented, or readily implementable, for many ASM participants.

In the CY 2026 PFS proposed rule (90 FR 32594), we considered the alternative of allowing identified ASM participants without CEHRT to opt-out of participating in ASM. However, we were concerned an opt-out would: (1) disincentivize the adoption of CEHRT and participation of specialists in value-based payment models, (2) be challenging for CMS to operationalize and audit, and (3) potentially result in a reduction in participant volume that would significantly affect ASM's impact and evaluability. We recognized there are underlying reasons why certain practices have yet to adopt CEHRT and that these practices currently not on CEHRT may share certain characteristics, such as smaller practice sizes with 15 or fewer clinicians, as defined at § 414.1305. To support these practices, we proposed additional policies and flexibilities in ASM, such as the complex patient scoring payment adjustment described in section III.C.2.e.(3) of this final rule and the small practice scoring adjustment described in section III.C.2.e.(4) of this final rule, with the goal of not inadvertently penalizing these practices, particularly those who disproportionally care for populations with higher medical complexity and greater social needs. We also considered the alternative of requiring CEHRT but not requiring CEHRT-related attestations and requirements mentioned earlier, such as the Security Risk Assessment and High Priority Practices Guide of SAFER Guides measures. We decided to include them given they help ensure safer and more meaningful use of CEHRT amongst ASM participants. Because they have been a consistent part of MIPS

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[279] SAFER Guides. *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2025-MIPS-Promoting-Interoperability-Measure-High-Priority-Practices-Guide-of-SAFER-Guides.pdf.*

reporting in the past, we anticipated that ASM participants are likely familiar with these attestations and measures, which could help reduce burden.

In the CY 2026 PFS proposed rule (90 FR 32594), we also considered the alternative of not requiring CEHRT to achieve a Promoting Interoperability ASM performance category score greater than zero. However, we were concerned this would deviate from existing MIPS policy and may disincentivize CEHRT adoption among ASM participants. Furthermore, we believe that requiring CEHRT to achieve a Promoting Interoperability ASM performance category score underscores the role CEHRT plays in providing foundational IT capabilities to enable the reporting of quality data and inclusion of additional IT functionality, such as e-prescribing and health information exchange (HIE), which is captured in ASM's Promoting Interoperability measures. CEHRT use plays an important role in helping ASM participants improve and transform care for Medicare beneficiaries with chronic conditions, whether through electronic clinical decision support, physician order entry or exchanging electronic health information with other clinicians or health care settings.

Lastly, in the CY 2026 PFS proposed rule (90 FR 32594), we considered inclusion of an affirmative attestation to The Actions to Limit or Restrict Compatibility or Interoperability of CEHRT measure in ASM to receive a score greater zero in the Promoting Interoperability ASM performance category as it would help ensure that ASM participants are acting in good faith when implementing and using CEHRT to exchange electronic health information, and not knowingly and willfully taking action to limit or restrict the compatibility or interoperability of CEHRT.

We requested comments on our proposals to require that ASM participants use CEHRT to receive a score for the ASM Promoting Interoperability performance category. We also sought comments on the definition of meaningful EHR user and other alternatives discussed in this section of this final rule that would be required for ASM participants to achieve a Promoting Interoperability ASM performance category score greater than zero; this includes allowing for a CEHRT-related opt-out, not requiring CEHRT, and requiring the Actions to Limit or Restrict Compatibility or Interoperability of CEHRT attestation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to require the use of CEHRT for the Promoting Interoperability ASM performance category. A commenter shared their belief that CEHRT requirement would ensure standardized data exchange across clinicians.

Response: We appreciate the commenters for their support for the use of CEHRT in ASM.

Comment: A commenter recommended that CMS take full advantage of the flexibility to demonstrate use of CEHRT (for example, a straightforward attestation) found in The Health Information Technology for Economic and Clinical Health (HITECH) Act.

Response: We appreciate the commenters for their recommendation. We believe that attestation to demonstrate use of CEHRT in ASM is straightforward and not burdensome; participants would be required to provide their EHR's CMS identification ID from the Certified Health IT Product List, available on *HealthIT.gov*. This is the same process currently in place for MIPS and should be familiar to ASM participants. In addition, we want to emphasize that ASM builds on the work done as a result of the HITECH Act. Notably, ASM aligns with the definition of CEHRT at § 414.1305, which was created in collaboration with the Office of the National Coordinator for Health Information Technology (ONC), now the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health IT (ASTP/ONC). The HITECH Act required ONC to establish the Health IT Certification Program, which CMS' definition for CEHRT at § 414.1305 cross-references.

Comment: A few commenters did not support the use of CEHRT in ASM. A commenter expressed concern that CEHRT may contain errors in medication prescribing, diagnoses, and treatments, resulting in physicians being unfairly penalized for errors beyond their control. Another commenter did not support CMS' concerns that providing flexibility in CEHRT reporting for ASM participants may disincentivize CEHRT adoption, noting that it does not consider the reality that the clinician relationship to CEHRT contains a multitude of factors above Medicare value-based payment reporting. The commenter recommended additional time and investment before CMS can rely on CEHRT to provide an accurate depiction of clinical decision making and patient care in surgery centers. Another commenter expressed concern that Ambulatory Surgery Centers (ASCs) may not have the necessary EHR or operational capabilities to successfully participate in a model that relies on CEHRT. A commenter

recommended that CMS provide additional information on the impact of low utilization of EHR and CEHRT in the Ambulatory Surgery Center setting on ASM overall.

Response: We appreciate the commenters for sharing their concerns and recommendations regarding the use of CEHRT, including in ASCs. While we recognize that EHRs may contain documentation errors or may not have all functionality to comprehensively support clinical decision making and patient care in surgery centers, we disagree that this should preclude incentivizing adoption of CEHRT in ASM and that CEHRT cannot currently be relied on without additional time or investment. CEHRT, as a baseline, promotes more standardized ways of storing, capturing, and sharing data in a structured format to aid patient care. We believe it is important to align with our Promoting Interoperability programs that require and incentivize CEHRT adoption to help improve interoperability, especially as the exchange of data captured through CEHRT can be critical to enabling seamless, high-quality patient care across different settings of care, including in and out of ASCs. We recognize that clinicians may want or need additional functionality beyond the defined standards and certification criteria associated with CEHRT to support more nuanced clinical decision-making or to improve documentation integrity; if desired, clinicians, health care organizations, and EHR vendors can further collaborate to develop and implement these additional solutions on-the-ground. We otherwise may consider inclusion of additional functionality beyond CEHRT in ASM in future rulemaking.

We also recognize the decision to adopt CEHRT can be multifactorial and can extend beyond participation in Medicare value-based payment programs. We disagree that clinicians and practices, including ASCs as a whole lack the capacity to adopt CEHRT, but we acknowledge that certain practices, such as smaller practices or practices with fewer resources that may be caring for more complex patient populations, could face greater challenges when it comes to CEHRT adoption. For those reasons, additional policies are outlined in sections III.C.2.e.(3) and III.C.2.e.(4) of this final rule that discuss the complex patient scoring adjustment and small practice scoring adjustment as well as in section III.C.2.d.(1)(b) of this final rule that discusses allowing flexibility for small practices to report quality measures in the quality ASM performance category at the TIN-level to help these clinicians and practices sustain investments in CEHRT and other infrastructure; in particular, clinicians practicing in ASCs who meet these criteria would be eligible. Regarding ASCs in particular, we disagree that ASCs as a whole

have low EHR utilization. While recent data related to the use of EHRs and CEHRT in different settings are limited, a survey by the Ambulatory Surgery Center Association in July 2025 found that 76 percent of ASCs use EHRs, an increase from 64 percent in 2023 and 55 percent in 2021.[280] This is complemented by 96 percent of hospitals and 78 percent of office-based physicians using CEHRT as of 2021.[281] Furthermore, we note that given ASM is focused on the longitudinal management of targeted chronic conditions, including the surgical and non-surgical treatment of low back pain, we anticipate the majority of ASM participants meeting ASM's eligibility and attribution criteria as defined in section III.C.2.s will not be practicing solely in ASCs.

As a result, we are not finalizing any alternative policies for not requiring CEHRT to achieve a Promoting Interoperability score greater than zero or to allow for a CEHRT-related opt-out from ASM.

Comment: A commenter recommended CMS should require other clinicians and developers of CEHRT be prohibited from information blocking electronic health information to pharmacists and penalize developers for doing so. The commenter noted information blocking causes delays in patient care and prevents clinicians from having a complete picture of the patient's health, which can lead to inefficient and ineffective care.

Response: We appreciate the commenters for their recommendation and agree that information blocking can lead to ineffective exchange of information that can result in adverse effects on patient care. This applies not only to data exchange with pharmacists but also with other clinicians, including with ASM participants. Accurate and timely data exchange is not only critical to patient care delivered by various interdisciplinary team members, but also when patients traverse multiple settings of care, from physician offices to hospitals to post-acute care facilities to patients' homes and communities. Information blocking by an EHR vendor or by any clinician or care team member working in any setting may result in delayed, inefficient, lower quality care and increased health care costs, which are counter to the goals of ASM. As a result, we believe in holding ASM participants accountable to not knowingly or willingly have taken action to limit or restrict the compatibility or interoperability of their CEHRT. We

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[280] Taira A. ASCA Survey Shows Continued Growth of EHR Usage by ASCs. ASC Focus: The ASCA Journal. Published August 21, 2025. https://www.ascfocus.org/ascfocus/content/articles-content/articles/2025/digital-debut/asca-survey-shows-continued-growth-of-ehr-usage-by-ascs. Accessed October 02, 2025.

[281] Office of the National Coordinator for Health Information Technology. "National Trends in Hospital and Physician Adoption of Electronic Health Records," Health IT Quick-Stat #61. https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records. Accessed October 02, 2025.

are finalizing our alternative to include the Actions to Limit or Restrict Compatibility or Interoperability of CEHRT attestation in ASM at § 512.740(b)(4)(ii), which creates alignment between ASM and MIPS and promotes consistency across our Promoting Interoperability programs. Of note, inclusion of this attestation does not imply inclusion of the broader information blocking requirements created by the 21st Century Cures Act in ASM.

After consideration of public comments, we are finalizing our proposal to require use of CEHRT at § 512.740(b)(1) as well as our alternative for which we sought comments that the ASM participant must attest to the "Actions to Limit or Restrict Compatibility or Interoperability of CEHRT" at § 512.740(b)(4)(ii). to receive a score greater than zero in the Promoting Interoperability ASM performance category.

We received no comments on our definition of "meaningful EHR user" and are therefore finalizing this provision without modification at § 512.705.

We also received no comments on our proposal that an ASM participant must complete the ONC direct review attestation to receive a score greater zero in the Promoting Interoperability ASM performance category and are therefore finalizing this provision without modification at § 512.740(b)(4)(i).

In addition, we received no comments on our proposal that an ASM participant must complete the activities included in the Security Risk Analysis measure within the calendar year of the ASM performance year to receive a score greater zero in the Promoting Interoperability ASM performance category and are therefore finalizing this provision without modification at § 512.740(b)(3)(ii).

Lastly, we received no comments on our proposal the ASM participant must attest to completion of the annual self-assessment under the High Priority Practices Guides of SAFER Guides measure within the calendar year of the ASM performance year to receive a score greater zero in the Promoting Interoperability ASM performance category and are finalizing this provision without modification at § 512.740(b)(3)(iii).

(ii) Promoting Interoperability Objectives and Measures

As discussed in the CY 2026 PFS proposed rule (90 FR 32594 through 32597), to receive a score for the Promoting Interoperability ASM performance category, an ASM participant must complete the

relevant attestations and measures related to CEHRT and report Promoting Interoperability objectives and measures. Our Promoting Interoperability objectives and measures align with the goals, objectives, and measures used in other programs, including in MIPS. We proposed at § 512.740(b)(2) that an ASM participant must report on MIPS Promoting Interoperability objectives and measures specified by CMS to assess performance in the Promoting Interoperability ASM performance category.

We proposed at § 512.740(b)(3)(i) that an ASM participant must fulfill the following requirements to earn an ASM performance category score for the Promoting Interoperability ASM performance category: For each measure, as applicable, ASM participants would report the numerator (of at least one) and denominator, or yes/no statement or an exclusion for each measure that includes an option for an exclusion. As described in the CY 2026 PFS proposed rule (90 FR 32595), we proposed for ASM participants to report all Promoting Interoperability measures at the TIN/NPI level, which is consistent with the methodology used to identify eligible ASM participants, as described in section III.C.2.c.(3)(a)(i) of this final rule. In the CY 2026 PFS proposed rule (90 FR 32595), we also considered allowing for TIN-level reporting for Promoting Interoperability measures but decided then to prioritize maintaining individual accountability and robust comparisons among ASM heart failure participants or ASM low back pain participants. We proposed at §§ 512.740(b)(2)(i) through (iv) that ASM participants must attest to the objectives and associated measures for the ASM performance year. The Promoting Interoperability measures would support the following objectives: Electronic Prescribing, HIE, Provider to Patient Exchange, and Public Health and Clinical Data Exchange, as shown in Table B-D6. The objectives would encourage leveraging the electronic exchange of health information, with a focus on the safety associated with prescribing medications, communication between clinicians, patient access to their health information, and reporting essential health data to public health agencies.

TABLE B-D6: PROMOTING INTEROPERABILITY MEASURES

Objectives	Measures		Available Points (based on performance)	Redistribution if exclusion is claimed
e-Prescribing	e-Prescribing		1-10 points	10 points to HIE objective
	Query of PDMP		10 points	10 points to the e-Prescribing measure
Health Information Exchange (HIE)	Option 1	Support Electronic Referral Loops by Sending Health Information	1-15 points	15 points to Provide Patients Electronic Access to Their Health Information measure
		Support Electronic Referral Loops by Receiving and Reconciling Health Information	1-15 points	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	Option 2	HIE Bi-Directional Exchange	30 points	No exclusion
	Option 3	Enabling Exchange under TECFA	30 points	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information		1-25 points	No exclusion
Public Health and Clinical Data Exchange	Report to the following public health or clinical data registries: 1. Immunization Registry Reporting 2. Electronic Case Reporting		25 points for the objective	25 points to the Provide Patients Electronic Access to their Health Information measure if an exclusion is claimed for both measures.
	Option to report one of the following public health agency or clinical data registry measures: • Public Health Registry Reporting, OR • Clinical Data Registry Reporting, OR • Syndromic Surveillance Reporting		No bonus points	Not applicable

As discussed, in section III.C.2.d.(5).(b) of this final rule, ASM participants would be required to submit collected data for the required measures in each objective (unless an applicable exclusion is claimed) for the same 180 continuous days (or more) during the calendar year. As discussed in the CY 2026 PFS proposed rule (90 FR 32595), given these measures have remained consistent in MIPS, as stated at § 414.1375(b)(2), ASM participants who participated in MIPS would likely be familiar with and implemented these measure specifications. As noted in the CY 2026 PFS proposed rule (90 FR 32595), we believe these measures align with the goals of ASM and reflect meaningful use of CEHRT. Electronic prescribing and provider to patient exchange, for example, through a patient portal, support patient-centered care and improve communication between patients and clinicians. Interoperability is needed for

effective collaboration between specialists and PCPs (aligning with the goals and activities of ASM's Improvement Activities), comprehensive care coordination, and seamless transitions of care.

Of the measures in the Public Health and Clinical Data Exchange category in MIPS, we proposed at § 512.740(b)(2)(iv) including the required MIPS measures only (Immunization Registry Reporting and Electronic Case Reporting) in ASM as they provide critical information to the mission and operations of our public health agencies. As described in the CY 2026 PFS proposed rule (90 FR 32596), the other measures in this category (Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting) would remain optional in ASM. Given these measures have been a stable part of the MIPS Promoting Interoperability measure set, keeping them optional allows for ease of reporting for ASM participants who may already have developed workflows and infrastructure to capture this data.

(iii) Adding, Removing, and Modifying Measures

In the CY 2026 PFS proposed rule (90 FR 32596), we proposed to avoid making significant changes to these measure sets over the period of model; however, we may propose to add or remove measures in response to relevant public comments, recommendations from ASM participants and interested parties, new CMS program activities, or significant changes made to the MIPS Promoting Interoperability measures set through rulemaking. Of note, because the measures currently proposed are all part of MIPS, any technical updates CMS applies to the measure specifications within MIPS would be incorporated into the Promoting Interoperability ASM measure sets accordingly (without rulemaking). Alternatively, we considered requiring notice and comment rulemaking before adopting any modifications made to the measures' specifications during rulemaking for MIPS.

We solicited public comments on these proposals on the Promoting Interoperability ASM performance category measures and objectives, including our proposal to add, remove, or modify measures in the Promoting Interoperability ASM performance category through rulemaking but to align with the MIPS technical specifications without rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received related to the Promoting Interoperability ASM performance category measures and objectives and our responses.

Comment: A commenter recommended suppressing the Electronic Case Reporting measure in ASM to avoid confusion, as it was also proposed for suppression in the QPP program.

Response: We appreciate the commenter for their recommendation. The CY 2026 PFS proposed rule (90 FR 32734 through 32736) included a proposal to suppress the Electronic Case Reporting measure for the CY 2025 performance year and the EHR reporting period in CY 2025 in MIPS due to the Centers for Disease Control and Prevention temporarily pausing electronic case reporting registration and onboarding of new health care organizations to establish a more efficient and automated process. This is not currently applicable to ASM given ASM's first performance year is not until 2027. That being said, we will continue to monitor updates to this measure as ASM's first performance year approaches with the goal of continuing to maintain alignment with the MIPS Promoting Interoperability performance category where possible and we may propose changes to this measure in ASM in the future.

Comment: A commenter supported the proposed approach to align the requirements for the Promoting Interoperability ASM performance category with MIPS requirements. The commenter expressed concerns with the requirement to report all Promoting Interoperability measures at the TIN/NPI level, noting that measures and objectives are coordinated at a facility level and reporting at the individual level does not provide useful information. Another commenter supported a group reporting approach so that an ASM participant can "count" a clinical action taken by another clinician in their group towards a PI measure. The commenter acknowledged that this is appropriate since the patient's care is managed within the same TIN, and requiring clinicians to repeat clinical actions at the individual level would be duplicative, increase burden, and potentially cause confusion for patients.

Response: We appreciate the commenters for their support and appreciate the commenters' suggestions on TIN-level reporting for Promoting Interoperability measures in ASM. We agree that TIN-level reporting may be less burdensome to clinicians and could better capture team-based activities and investments in infrastructure; this could result in more streamlined workflows and potentially less confusion for clinicians and patients. As discussed in section III.C.2.d.(1).(b) of this final rule, we are finalizing Promoting Interoperability ASM performance category requirements to be fulfilled by ASM participants via TIN-level reporting.

Comment: A commenter supports the policy where any future changes to the Promoting

Interoperability ASM performance category should be made through a notice and comment rulemaking process. The commenter supports consistency in methodology across programs but notes there may be certain circumstances that would warrant differences in policy across programs and at a minimum, notice and rulemaking would provide the appropriate awareness for model participants to know in advance which changes may be made year to year in methodology.

Response: We appreciate the commenters for their support for adopting changes to the Promoting Interoperability ASM performance category objectives and measures through notice and comment rulemaking. We agree this would give advanced notice to ASM participants and would allow ASM to add, remove, or modify any objectives or measures that may be less aligned with ASM's goals, due to operational considerations, or for other reasons. We want to clarify, as discussed in section III.C.2 d.(5)(c)(iii) of this final rule, that updates to the technical specifications made in MIPS for these objectives and measures would be adopted without notice and comment rulemaking in ASM. This allows ASM to align in a real-time manner with the most up-to-date technical versions of these measures and promote standardization across Promoting Interoperability programs. ASM would rely on the technical expertise across other programs involved in maintaining these measures and avoid duplicating those efforts. Therefore, we are not finalizing our alternative proposal to adopt changes to the technical specifications of ASM's Promoting Interoperability measures through rulemaking.

Comment: A commenter recommended maintaining the same measure set for the entire duration of the model for the Promoting Interoperability ASM performance category. The commenter noted that this could reduce the administrative burden for ASM participants and strengthen the reliability of longitudinal assessments of measures by ensuring consistent methodology over time.

Response: We appreciate the commenter for the suggestion. While we also support burden reduction and robust longitudinal assessments where possible, we disagree that we must maintain the same measure set for the Promoting Interoperability ASM performance category for the entire duration of ASM. We recognize the importance of alignment and consistency, particularly when it comes to operationalizing measure reporting, and thus, we decided to adopt existing MIPS Promoting Interoperability objectives and measures in ASM as opposed to requiring ASM participants to implement new measures. That being said, as discussed in section III.C.2.d.(5)(c)(iii), we believe we need a process

to add, remove, or modify the objectives and measures to ensure the performance category requirements continue to align with ASM's goals and give us flexibility to be able to respond to feedback and concerns from internal and external interested parties as well as account for any evolving circumstances.

After consideration of public comments, we are finalizing our proposal without modification that an ASM participant must comply with reporting requirements for each measure at § 512.740(b)(3)(i) and report on the Promoting Interoperability objective and measures specified by CMS to assess performance in the Promoting Interoperability ASM performance category at § 512.740(b)(2), including the objectives and measures at §§ 512.740(b)(2)(i) through (iv): Electronic Prescribing, HIE, Provider to Patient Exchange, and Public Health and Clinical Data Exchange.

(iv) Supporting Use of CEHRT

ASM aims to support the electronic exchange of health information using CEHRT to improve patient care and coordination of care.

We proposed at § 512.740(b)(4)(i)(A)(1) and (2) that the ASM participant support use of CEHRT by providing acknowledgement of the requirement to cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and if requested, cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field. Furthermore, we proposed at § 512.740(b)(4)(i)(B) that an ASM participant has the option to attest to the following objectives and measures: at § 512.740(b)(4)(i)(B)(1) that the ASM participant acknowledges the option to cooperate in good faith with ONC-ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC-ACB surveillance is received; and at § 512.740(b)(4)(i)(B)(2) if requested, that the ASM participant cooperate in good faith with ONC-ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the

definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field. These proposals (90 FR 32596) to support physicians with the performance of CEHRT aligns with requirements of the MIPS program as finalized at § 414.1375(b)(3)(i) through 414.1375(b)(3)(i)(B)(2).

We solicited comments on our policies supporting the use and performance of CEHRT via affirmative attestation to cooperating with the ONC direct review process. We did not receive public comments on this provision, and therefore, we are finalizing as proposed at § 512.740(b)(4)(i).

(d) Alternatives Considered for the Promoting Interoperability Reporting Requirements

CY 2026 PFS proposed rule (90 FR 32593 through 32597), we considered alternatives for the Promoting Interoperability reporting requirements. Our proposals mostly aligned with reporting requirements for the Promoting Interoperability performance category with the MIPS program for multiple reasons. Aligning with MIPS Promoting Interoperability objectives and measures where appropriate promotes standardization across CMS and its programs. Measure alignment can also reduce confusion, burden, and operational complexity for ASM participants by limiting the need for ASM participants to implement different specifications for potentially similar or related measures. Furthermore, the MIPS Promoting Interoperability measure set has been stable for several years and has been successfully reported in MIPS by most of its participants. Therefore, we do not believe it would be an undue burden for ASM participants to continue reporting these measures, particularly given they support the goals of ASM.

As discussed in the CY 2026 PFS proposed rule (90 FR 32596), in our first alternative, we considered requiring reporting for CEHRT attestation, the ONC direct review Attestation, the Security Risk Assessment Measure, and the High Priority Practices Guide of the SAFER Guides Measure; each of these items is required in MIPS to get a Promoting Interoperability performance category score greater than zero. This option would not require specific reporting of other Promoting Interoperability measures.

We also considered a second alternative that would require the attestations in the first alternative as well as reporting one of the Health Information Exchange options. We believe this option would emphasize the importance of exchanging health information seamlessly to the ASM.

A third alternative we considered was to adopt, by reference, the provisions of MIPS for the PI category, including both the measures and scoring policies. We also considered deferring the PI category measures within ASM to the PI category within MIPS such that the ASM would automatically update to align with MIPS for each future ASM performance year. Aligning with the PI category within MIPS would reduce complexity for ASM participants, especially those who have been participating in MIPS. While we believe this would limit confusion and align objectives across CMS, we decided that this could introduce risk to ASM insofar changes to the PI category could be introduced in MIPS that may not align with ASM's goals and priorities; in these cases, ASM could consider not adopting or delaying adoption of these changes. We believe that maintaining the PI category in ASM through rulemaking would be the better approach; however, we invite comment on the merits of ASM deferring measure selection and scoring to the MIPS PI category.

A fourth alternative we considered was to develop new Promoting Interoperability measures specific to ASM. While new measures could potentially more meaningfully capture the use of health IT in patient care, we were concerned about the feasibility of new measure development and the operational challenges that would be imposed on ASM participants and their EHR vendors to implement these new measures.

We solicited comments on our alternatives, including only requiring attestations related to CEHRT use (without or without the Health Information Exchange objective), adopting the PI category in MIPS in its entirety, and developing new Promoting Interoperability measures specific to ASM

We received public comments on these proposals. The following is a summary of the comments we received on alternative requirements for the Promoting Interoperability ASM performance category and our responses.

Comment: A few commenters supported the alternative to only require attestations related to CEHRT. A commenter recommended that ASM should be focused on improving quality of care and outcomes for heart failure and lower back pain patients, noting concern that requiring the full MIPS Promoting Interoperability performance category scoring and measure policies would detract from ASM's primary goals.

Response: We appreciate the commenters for their support of this alternative proposal. While we

recognize that only requiring the CEHRT-related attestations helps alleviate reporting burden, not requiring reporting of the Promoting Interoperability objectives and measures results in this performance category becoming less meaningful. We disagree that these measures detract from ASM's goals, one of ASM's primary goals is to improve primary and specialty care integration which requires advancing interoperability, whether it be through use of a Health Information Exchange or e-prescribing or sharing electronic data securely with patients or public health agencies. We believe it is also important to capture performance related to health IT beyond CEHRT use only. Given that we are aligning with existing MIPS measures that have been stable and successfully reported in the past by the majority of their participants, many of whom will be ASM participants, we believe this will limit the burden associated with implementing new or different Promoting Interoperability measures. Therefore, we are not finalizing the alternative proposals to only require reporting of CEHRT and CEHRT-related attestations, including with and without the Health Information Exchange objective.

Comment: A few commenters shared recommendations on this proposal to develop new measures specific to ASM in the Promoting Interoperability performance category. A commenter suggested CMS include metrics in ASM that support sharing information with pharmacists and ensure all clinicians have access to CEHRT for seamless data exchange. Another commenter recommended developing specific Promoting Interoperability measures related to heart failure and low back pain, and measures that enhance interoperability. A commenter expressed concern that the MIPS measures are too limiting, especially given CEHRT is already widely in use, and that it could unintentionally discourage adoption of remote patient monitoring or telemedicine tools, noting that patient engagement and interoperability are vital for value-based care and suggested that information blocking and HIPAA regulations offer more meaningful incentives.

Response: We appreciate the commenters for their support of the proposal to develop new Promoting Interoperability measures. We believe the e-prescribing and Health Information Exchange objectives described in section III.C.2.d.(5).(c).(ii) of this final rule help support and capture information sharing with pharmacists. ASM also incentivizes the adoption of CEHRT by ASM participants by requiring it to achieve a score greater than zero in the Promoting Interoperability ASM performance category, as discussed in section III.C.2.d.(5).(c).(i) of this final rule; this aligns with other CMS

programs and can help increase systemic adoption of CEHRT. ASM seeks to complement other regulatory requirements, such as HIPAA, including any of its incentives. While we recognize there may be opportunities to develop and implement more condition-specific Promoting Interoperability measures, we believe the finalized measure set at § 512.740(b)(2) captures performance for a set of baseline interoperability functions that are applicable to all ASM participants caring for beneficiaries with heart failure and low back pain without imposing undue burden on them. New measure implementation is resource intensive, and we are concerned that some ASM participants may face operational challenges and that those with fewer resources may be at a disadvantage. That being said, ASM participants can consider adoption of additional technologies, such as remote monitoring or telemedicine tools, beyond these measures, and we may consider additional incentives or measures related to this in the future. However, due to concerns related to operationalizing new measure development and increased ASM participant burden, we are not finalizing this alternative proposal to require reporting of new Promoting Interoperability measures in ASM.

Comment: A few commenters supported adopting the full MIPS Promoting Interoperability category and its scoring policies for ASM, including applying any future updates to the category throughout the model's performance years.

Response: We appreciate the commenters for their support of this alternative proposal. While we recognize that adopting the full MIPS Promoting Interoperability category in ASM can streamline reporting and promote standardization, it does not provide any flexibility for the model to tailor requirements to ensure they align with ASM's goals and priorities, including the deviations introduced in section III.C.2.d.(5) of this final rule. This includes situations where there are changes in the future to the MIPS category that are less applicable to ASM participants or other features specific to ASM participants (and less relevant to MIPS) that ASM may want to introduce. As a result, we are not finalizing this alternative proposal to adopt the full MIPS Promoting Interoperability category, by reference, into ASM.

After consideration of public comments, we are not finalizing any of these alternative proposals related to Promoting Interoperability ASM performance category requirements

(e) Promoting Interoperability ASM Performance Category Scoring

We proposed at § 512.740(c)(1) an ASM participant earns a score for each measure by fulfilling the reporting requirements specified at § 512.740(b) and if an exclusion, under the measure's specifications as maintained and published by MIPS, is reported for a measure, the points available for that measure are redistributed to another measure, as specified in Table B-D6. We proposed at § 512.740(c)(1)(i) maintaining the score amounts and applicable redistribution scoring policies for each required measure as set forth in the MIPS measure specifications. We refer readers to Table B-D6 for the scores assigned to each measure as defined in the MIPS measure specifications. We considered the alternative of developing an ASM-specific scoring system that assigns different scores to each Promoting Interoperability measure. However, we were concerned this would deviate from MIPS, which is likely already familiar to ASM participants. Furthermore, the existing scoring in MIPS already reflects ASM's priorities, for example, with more measure achievement points assigned to the Health Information Exchange category compared to the others.

As stated earlier in section III.C.2.d.(5).(ii) and consistent with MIPS, the optional Public Health and Clinical Data Exchange measures (Public Health Registry Reporting, Clinical Data Registry Reporting, or Syndromic Surveillance Reporting) in ASM would remain optional in ASM. In the CY 2026 PFS proposed rule (90 FR 32597), we discussed not adopting the MIPS scoring policy of assigning 5 bonus points for submitting a "yes" response for any of the optional Public Health and Clinical Data Exchange measures given they may be less relevant to the care provided to Medicare beneficiaries by ASM participant, for example, engaging with a public health agency to submit syndromic surveillance data from an urgent care setting. In addition, bonus points may signal greater importance of these measures over other Promoting Interoperability measures that more directly support ASM's goals, such as interoperability to support primary and specialty care integration. We continue to capture essential public health reporting activities on immunizations and reportable conditions in the two required Public Health and Clinical Data Exchange Promoting Interoperability measures.

We proposed at § 512.740(c)(2) that unless otherwise specified by CMS, provided an ASM participant meets the CEHRT requirements as described in section III.C.2.d.(5).(b), CMS sums the scores for each of the required Promoting Interoperability measures described at § 512.740(b) and divides this

sum by the total number of available Promoting Interoperability points to determine the ASM Promoting Interoperability performance category score. The ASM Promoting Interoperability performance category score cannot exceed 100 percent. If an ASM participant does not demonstrate meaningful CEHRT use as described in section III.C.2.d.(5).(c)of this final rule, they would receive a zero for their Promoting Interoperability ASM performance category score. The Promoting Interoperability ASM performance category score would be used as a Promoting Interoperability performance category scoring adjustment to the final score specified under § 512.745(a)(1)(iv).

In the CY 2026 PFS proposed rule (90 FR 32597), we considered automatically applying a score of zero for an ASM participant's Promoting Interoperability performance score for any ASM participant who did not achieve full points on the Promoting Interoperability performance category. However, we recognized it is important to acknowledge and credit the achieved points on the individual measures. Therefore, we would leverage the Promoting Interoperability performance category score for the Promoting Interoperability performance category scoring adjustments to the ASM final score, as discussed in section III.C.2.e.(1) of this final rule. The concepts represented in these Promoting Interoperability requirements support ASM participants in improving patient care while maintaining or lowering cost of care.

In the CY 2026 PFS proposed rule (90 FR 32597), we did not propose any exceptions for the Promoting Interoperability ASM performance category requirements. CMS has established automatic reweighting criteria of the Promoting Interoperability category in MIPS at § 414.1380(c)(2)(i)(C)(9) for certain MIPS eligible clinicians, such as hospital-based clinicians and Ambulatory Surgical Center-based clinicians, and for clinicians in small practices as defined in § 414.1305. The MIPS reweighting policy generally excludes the Promoting Interoperability performance category from the MIPS final score if the applicable clinician or group practice who meets automatic reweighting criteria does not submit Promoting Interoperability data. Due to ASM's participant selection criteria (see section III.C.2.c.(3). of this final rule), many ASM participants, except for those in small practices with 15 or fewer clinicians, will not qualify for this automatic reweighting criterion if they were to be considered eligible clinicians under MIPS. For ASM participants in small practices or solo practitioner ASM participants, we are adjusting their final scores as described in section III.C.2.e.(4) of this final rule and allowing for

flexibility for reporting quality measures at the TIN-level as detailed in section III.C.2.d.(1).(b) of this final rule. We believe the potential confusion and complexity to develop and implement an exclusion policy for the Promoting Interoperability ASM performance category would outweigh any potential benefits it would have for a likely small number of ASM participants.

Lastly, we proposed an Extreme and Uncontrollable Circumstances policy at § 512.780 and discussed in section III.C.2.i. of this final rule, but we did not propose to include a Promoting Interoperability-specific hardship application in ASM in the CY 2026 PFS proposed rule (90 FR 32597) Data analysis of 2023 data submitted by clinicians who participated in MIPS that would have met the ASM participant selection criteria showed that less than 1 percent of those clinicians submitted a Promoting Interoperability-specific hardship application. The operational lift and resources needed to develop and maintain a hardship application for ASM likely outweigh the potential benefit only a few practices may receive.

We sought comments on these proposals to score the Promoting Interoperability ASM performance category.

We received public comments on these proposals. The following is a summary of the comments we received related to scoring the Promoting Interoperability ASM performance category and our responses.

Comment: A few commenters did not support the proposal to exclude bonus points for optional measures. A commenter recommended that CMS should allow ASM participants to be eligible for the same bonuses awarded for these measures in the MIPS program, noting their relevance for patients with chronic diseases such as HF. Another commenter shared their belief that awarding bonus points to facilities submitting data to Public Health Registries is essential for closing data gaps in rural communities and may encourage more EHR vendors to certify modules for these measures.

Response: We appreciate the commenters for their suggestions. While we recognize the role of the Public Health and Clinical Data Exchange measures in public health reporting and are thus, requiring two measures and allowing for reporting of the optional measures, we disagree that these optional measures should be incentivized in ASM by rewarding ASM participants bonus points for reporting. As discussed in section III.C.2.d.(5).(e) of this final rule, these measures are less relevant to the direct care

being delivered by the ASM participant to beneficiaries with heart failure and low back pain. For example, the Public Health Registry Reporting optional measure includes reporting data on cancer and antimicrobial use and resistance[282], which are clinical areas in which the majority of ASM cardiologists and ASM low back pain specialists are unlikely to spend large portions of their time working in; this would not be the case if ASM participants included oncologists and infectious disease specialists. Furthermore, we want to emphasize that the focus of ASM is on the outpatient setting and would encourage facilities and hospitals to continue to submit this data and receive bonus points as part of their participation in our other Promoting Interoperability programs, including for eligible hospitals and critical access hospitals (CAHs) located in rural areas. In addition, we are concerned that awarding bonus points for this category deprioritizes other goals in ASM that we are trying to actively incentivize, such as improved collaboration with primary care through interoperability and advancing patient outcomes through communicating via a patient portal or e-prescribing medications. As a result, we are not finalizing the inclusion of bonus points for reporting optional public health measures in ASM.

Comment: A few commenters recommended that CMS include MIPS special status designations and exceptions in the Promoting Interoperability ASM policies. Several commenters did not support the proposal to not apply a Promoting Interoperability hardship exception in ASM. A few commenters expressed concern that a lack of an exception could lead to inappropriate penalization of certain clinicians, such as anesthesiologists; may prevent clinicians from meeting Promoting Interoperability ASM requirements; may undermine the objectives of the model; would create misalignment between ASM and MIPS; and could result in clinicians not accepting Medicare patients.

Response: We appreciate the commenters for their feedback. While not implementing the automatic weighting criteria and hardship application in ASM is a deviation from MIPS, we disagree they are needed in ASM. We believe that many of the MIPS criteria related to automatic reweighting and hardship exceptions would not be applicable to ASM participants as defined by our participant criteria discussed in sections III.C.2.c.(2) and III.C.2.c.(3) in this final rule. For example, as part of the EBCM methodology, a specialist with a relevant specialty type would have needed to have billed 30 percent of

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[282] Centers for Disease Control. "Public Health Registries Reporting." Published December 17, 2024. https://www.cdc.gov/data-interoperability/php/about/public-health-registries-reporting.html. Accessed October 02, 2025.

triggering or confirming codes on Part B Physician/Supplier claim lines related to the ASM condition for the beneficiary in addition to having at least 20 EBCM episodes attributed to them to participate in ASM. Therefore, the majority of physicians who are non-patient-facing or facility-based or ASC-based, such as anesthesiologists only working in the Operating Room, and who would have been considered for automatic reweighting in MIPS will likely not meet participation criteria for ASM as outlined in sections III.C.2.c.(2) and III.C.2.c.(3) in this final rule. Meanwhile, ASM participants working in small practices with 15 or fewer clinicians, who would receive automatic reweighting in MIPS, will receive a small practice scoring adjustment in ASM to try to prevent inappropriate penalization, as described in section III.C.2.e.(4) of this final rule; ASM participants in small practices will also receive flexibility to report quality measures in the quality ASM performance category at the TIN-level as discussed in section III.C.2.d.(1).(b) of this final rule, which can help reduce burden.

We disagree that lacking a hardship exception (as operationalized in MIPS) would undermine ASM's goals. ASM will enforce an Extreme and Uncontrollable Circumstances policy at § 512.780 (and discussed in section III.C.2.i. of this final rule), which will account for weather disasters and other circumstances that would be covered under a MIPS Promoting Interoperability hardship exception. ASM otherwise aims to incentivize adoption of CEHRT and promote interoperability and we believe that offering a hardship exception – which had very low uptake historically amongst MIPS clinicians that would have met ASM participation criteria (as discussed in section III.C.2.d.(5).(e) of this final rule) – undermines that goal. Given CEHRT helps enable success in other ASM performance categories, such as reporting quality data or performing care coordination with primary care, we believe it is important that ASM participants meet, rather than be exempted from, the Promoting Interoperability ASM performance category requirements.

After consideration of public comments, we are finalizing our proposal without modification for scoring the Promoting Interoperability ASM performance category at § 512.740(c).

e. Final Score Methodology

In this section, we proposed a scoring methodology for assessing the total performance of each ASM participant (referred to as a "final score") that allows for accountability and alignment for performance within each ASM cohort. Specifically, we proposed to define at § 512.705 "final score" to

mean a composite assessment (using a scoring scale of zero to 100 points) for each ASM participant for an ASM performance year determined using the methodology for assessing the total performance of an ASM participant according to performance standards for applicable measures and activities for each ASM performance category as described in § 512.745.

The methodology discussed in this section would calculate a final score based on the quality and cost ASM performance categories scores for each ASM participant while considering negative scoring adjustments for the improvement activities and Promoting Interoperability ASM performance categories. Additional points would be added to the final score for ASM participants that address complex care and ASM participants that are part of small practices. Later in this section of the final rule, we proposed specific data submission requirements for ASM participants to receive a final score. ASM participants that do not meet these minimum data submission requirements would receive a final score of zero, which would lead to the maximum negative payment adjustment applicable for the corresponding ASM payment year. We also proposed that ASM participants who meet the data submission requirements to receive a final score but cannot be measured on quality or cost performance would not receive a final score and would therefore receive a neutral payment adjustment.

Specifically, we proposed at § 512.745(a) to calculate a final score of zero to 100 points using the formula we proposed in section III.C.2.e.(5) of this final rule and specified at § 512.745(a)(5) for each ASM participant that meets the requirements to receive a final score as proposed in section III.C.2.e.(2) of this final rule and specified at § 512.745(a)(2). We proposed policies to determine scores for the ASM performance categories in sections III.C.2.d.(2) through III.C.2.d.(5) of this final rule. ASM performance category scores reflect the assessment of each ASM participant's performance on the applicable measures and activities for an ASM performance category for its applicable performance period based on the performance standards for those measures and activities.

We would use the final score to determine an ASM payment adjustment factor for the ASM participant for the applicable ASM payment year as discussed in section III.C.2.f. of this final rule.

(1) ASM Performance Category Weights and Scoring Adjustments

To create a final score from zero to 100 based on the individual ASM performance category scores, we proposed at § 512.745(a)(1)(i) through (iv) to assign an ASM performance category weight of

50 percent to each of the quality and cost ASM performance categories and to apply adjustments to the final score based on scores in the improvement activities and Promoting Interoperability ASM performance categories. Accordingly, we proposed that the improvement activities and Promoting Interoperability ASM performance categories would not have a performance category weight but would have separately applied scoring adjustments that are potentially applied to the final score. The proposed weights for the quality and cost ASM performance categories, as well as the improvement activities and Promoting Interoperability ASM performance category scoring adjustments are described in Table B-D7.

TABLE B-D7: ASM PERFORMANCE CATEGORY SCORING WEIGHTS AND ADJUSTMENTS BY ASM PERFORMANCE CATEGORY

ASM Performance Category	Weight or Scoring Adjustment in Final Score
Quality	50 percent weight
Cost	50 percent weight
Improvement Activity	Scoring adjustment of zero, -10, or -20 points
Promoting Interoperability	Scoring adjustment of zero to -10 points

We proposed to only add weights to the quality and cost ASM performance categories for the final score and to not add weights to the improvement activities and Promoting Interoperability ASM performance categories to broaden the distribution of final scores. Based on historical MIPS performance in the improvement activities and Promoting Interoperability performance categories, we believe ASM participants would be likely to achieve higher ASM performance category scores in these two performance categories. One of the stated goals of ASM is to increase two-sided risk and create payment adjustments of a higher magnitude for ASM participants to incentivize performance improvements. If final scores were clustered around a small range of performance scores, differentiating performance and operationalizing a wider range of payment adjustments could prove difficult.

We also proposed to weight the cost and quality ASM performance category scores at 50 percent each because those weights align with ASM's goal, as described in sections III.C.2.d.(2). and III.C.2.d.(3). of this final rule, of decreasing the cost of care for beneficiaries with ASM's targeted chronic conditions and improving quality care through a focused measure set relevant to ASM's clinical specialties and targeted chronic conditions. To drive cost and quality improvement as described in sections III.C.2.d.(2) and III.C.2.d.(3) of this final rule, we believe that weighting cost and quality ASM

performance category scores at 50 percent creates the necessary incentives to lower chronic condition cost of care while improving quality metrics.

We proposed at §§ 512.745(a)(1)(iii) and 512.745(a)(1)(iv) to introduce improvement activities and Promoting Interoperability scoring adjustments to the ASM participant's final score dependent on the performance in the improvement activities and Promoting Interoperability ASM performance categories. We proposed at § 512.745(a)(1)(iii)(A) that ASM participants that achieve a 100 percent score for the improvement activities ASM performance category would not receive an improvement activities ASM performance category scoring adjustment to their final scores. We proposed at § 512.745(a)(1)(iii)(B) that ASM participants that receive a 50 percent improvement activities ASM performance category score (that is, an ASM participant that attested to meeting the requirements of one of the two proposed required improvement activities) would receive an improvement activities ASM performance category scoring adjustment of negative 10 points to the final score specified at § 512.745(a). We proposed at § 512.745(a)(1)(iii)(C) that ASM participants that receive a zero percent improvement activities ASM performance category score would receive an improvement activities ASM performance category scoring adjustment of negative 20 points to the final score specified at § 512.745(a). The maximum improvement activities ASM performance category scoring adjustment would be negative 20 points.

To determine the Promoting Interoperability performance category scoring adjustment, we proposed at § 512.745(a)(1)(iv)(A) and (B) that we would multiply the Promoting Interoperability ASM performance category score by 100 then subtract that product from 100 and divide by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10 points. The maximum Promoting Interoperability ASM performance category scoring adjustment would be negative 10 points. For example, if an ASM participant's Promoting Interoperability ASM performance category score was 73 percent, we would multiply 73 percent by 100, subtract 73 from 100 and divide the score by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10, resulting in a negative Promoting Interoperability ASM performance category scoring adjustment of 2.7 points.

We considered weighting all the ASM performance category scores to determine a final score instead of proposing the scoring adjustments for the improvement activities and Promoting

Interoperability ASM performance category scores. Under this alternative, we considered the following ASM performance category weights to calculate the final score when there is no reweighting: (1) quality 30 percent; (2) cost 30 percent; (3) improvement activities 25 percent, and (4) Promoting Interoperability 15 percent. For similar reasons discussed earlier in this section of this final rule, we believe that increasing the weight on the improvement activities and decreasing the Promoting Interoperability ASM performance category weights relative to performance category weights in MVPs as defined at § 414.1365(e)(1) would increase the incentive to achieve the desired aims of improved primary care and specialty care integration under ASM. We believe that the improvement activities would be important to meet ASM's goal of better integrating specialty and PCPs as described in section III.C.2.d.(4) of this final rule. Ultimately, we believe that the proposed ASM performance category weights and scoring adjustments, as discussed earlier in this section of this proposed rule, would overcome the potential challenges in determining meaningful payment adjustments if final scores were clustered around a small range of performance scores.

We also considered using the same ASM performance category weights used by the Quality Payment Program to score performance categories in MVPs as defined at § 414.1365(e)(1) but without the potential for reweighting as defined at § 414.1365(e)(2) (89 FR 98345). As defined at § 414.1365(e)(1), MVPs use the following performance category weights to calculate the final score when there is no reweighting: (1) quality 30 percent; (2) cost 30 percent; (3) improvement activities 15 percent; and (4) Promoting Interoperability 25 percent. We believe that the improvement activities ASM performance category's goal of integrating specialty managed care with primary care specialists is central to ASM's larger goal. Therefore, a higher weight should be given to the improvement activities ASM performance category over the Promoting Interoperability ASM performance category.

We believe weighting the quality and cost performance categories at 50 percent more accurately assigns points in support of ASM's goals. With regards to the negative scoring adjustments, the improvement activities ASM performance category's goal of integrating specialty managed care with primary care specialists is central to ASM's larger goal. Therefore, a higher number of potential negative scoring adjustment points should be given to ASM participants that do not meet requirements of the

improvement activities ASM performance category over the Promoting Interoperability ASM performance category.

We solicited comments on our proposed ASM performance category weights and scoring adjustments as proposed at § 512.745(a)(1) and the alternative ASM performance category weights we considered in this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support CMS' proposal to score ASM participants exclusively on the quality and cost performance with equal weighting of 50 percent for each. A few commenters noted that CMS proposed to score specialists on quality and cost measures that only a few report, some of which their registries do not report. A few commenters noted that shifting individual clinicians into a model where 100 percent of scoring rests on quality and cost for a small ASM heart-failure cohort is a sharp departure from prior MIPS and MVP scoring, while also noting the low adoption rate of MVPs and need to better support clinicians transition to value-based care.

Response: We appreciate the commenters for their feedback on our scoring proposals. However, we disagree and believe that weighting the quality and cost ASM performance categories at 50 percent, respectively, properly distributes ASM participants' final scores to create meaningful ASM payment adjustments. We note that all cost and quality measures being finalized for use in ASM at this time are already reportable under MIPS. Creating like-to-like comparisons between similar providers requires participants to report on the same measures related to the same condition. We also acknowledge the commenters' desire for the ASM performance category weights and reweighting policy to match MIPS policies. Although we recognize that including the improvement activities and Promoting Interoperability ASM performance categories as scoring adjustments is different from MIPS, it is important to note that our scoring policy is not solely based on performance on the cost and quality categories. Cost and quality weights supplemented by zero or negative scoring adjustments from performance on the improvement activities and Promoting Interoperability performance categories are still used to determine an ASM participant's final score. We also believe that starting the model in CY 2027 gives appropriate time for ASM participants to begin adopting the right reporting mechanisms and registries to properly participate

in ASM and overcome the low adoption rate of MVPs amongst certain specialties, which we note is a voluntary reporting option under the Quality Payment Program.

Comment: A few commenters offered recommendations regarding the proposed weighting of the ASM performance categories. The commenters recommended that CMS lower the ASM cost category weight to 30 percent initially and phase in increases gradually over time, using a reasonable year-over-year glidepath to limit large swings. Another commenter recommended that all ASM performance categories should be linked to quality improvement, not solely cost. Additionally, a commenter recommended that CMS ensure alignment between cost and quality scoring to ensure that they accurately reflect outcomes and improvement.

Response: We appreciate the commenters' suggestions on the weighting of the cost ASM performance category and improvement scoring. However, we disagree that weighting the ASM cost performance category at 30 percent and incrementally raising it over time would reward the right behaviors. We want to reward participants for performance on lowering spending related to unnecessary or low-value services, and we believe a 30 percent weight creates an inadequate incentive to improve cost performance; therefore, we believe that a glidepath to a larger cost ASM performance category weight is unnecessary. All ASM performance categories directly contribute to an ASM participant's final score. We did not consider directly aligning cost and quality scoring because our cost and quality measures are aligned and accurately reflect outcomes and improvements in quality and spending.

Comment: Several commenters expressed concern that the proposed cost category weighting of 50 percent would inappropriately overemphasize the cost category. A few commenters noted that as proposed, a single EBCM would constitute 50 percent of the ASM participant's final score. A few commenters expressed concern that the proposed cost category weight, coupled with potential negative adjustments for the improvement activities and Promoting Interoperability ASM performance categories, would undermine quality improvement and run the risk of incentivizing cost-cutting over clinical quality. A few commenters expressed concern that the proposal would also inadvertently penalize providers delivering necessary, appropriately higher cost care. The commenters also shared their belief that the proposed cost category weighting could lead clinicians to avoid managing complex, high-acuity patients, and avoid resource-intensive but clinically appropriate settings like hospitals (including rural and critical

access facilities); such shifts in care could disadvantage clinicians serving patients from communities with lower incomes or have negative upstream influences on beneficiaries' health.

Response: We appreciate the commenters for their feedback on the weighting of the cost ASM performance category. However, we disagree and believe that weighting the cost category at 50 percent appropriately emphasizes participant's incentives to work to lower costs by identifying ways to reduce the provision of unnecessary or low-value services. As noted earlier in this section of this final rule, though the cost category and the applicable EBCM score compose 50 percent of an ASM participant's final score, their score receives potential neutral or downward adjustments depending on a participant's performance in the improvement activities and Promoting Interoperability performance categories. Those potential downward adjustments amount to 30 negative downward adjustment points, further stressing to participants that activities beyond reducing spend in the ASM cost performance category affect scoring. We stress that the EBCM's risk adjustment methodology accounts for patient acuity and complexity. The cost category weight would not penalize providers delivering necessary, higher cost care because the EBCM's risk adjustment methodology ensures that cost comparisons are not raw cost versus other physicians' costs. Rather, ASM participants risk standardized costs versus their peers' costs treating similar patients. The EBCM risk adjustment methodology uses clinical factors such as age, comorbidities, recent hospitalizations and other relevant conditions to standardize costs. Additionally, the EBCMs are structured so that if a provider inappropriately avoids admitting a patient to a clinically appropriate setting, such as a hospital, the patient is likely to eventually require an even costlier admission, ultimately driving up total episode costs. For these reasons, we believe that the use of a clinically relevant EBCM and the weighting of the cost ASM performance category would create an appropriate incentive to improve upstream chronic condition management to avoid costlier downstream services that would be attributed to an ASM participant through the EBCM attribution methodology.

Comment: A few commenters did not support the proposed ASM performance category scoring adjustments for Promoting Interoperability and improvement activities. The commenters recommended that clinicians have the opportunity to earn points towards their ASM final score based on their performance across all four performance categories, similar to their scoring under MIPS. A few commenters recommended that CMS allow for only positive scoring or credit in the improvement

activities and Promoting Interoperability ASM performance categories, rather than a neutral or reduced score. The commenters expressed concerns that the proposed scoring structure would create a structure that is punitive rather than supportive and could discourage participation in improvement activities and Promoting Interoperability, thus undermining the value of these activities while failing to promote comprehensive performance improvement. Additionally, commenters believe clinicians who exceed expectations in the improvement activities and Promoting Interoperability ASM performance categories should be rewarded, not penalized, especially since performance improvement takes time.

Response: We recognize the commenters' concerns regarding improvement activities and Promoting Interoperability ASM performance categories functioning solely as neutral or negative scoring adjustments as opposed to MIPS and MVPs where all performance categories contribute positively towards a participant's score. However, we disagree with the comment that this weighting approach is inappropriate for calculating ASM participants' final scores. We proposed applying weights only to the quality and cost categories, while leaving the improvement activities and Promoting Interoperability ASM performance categories unweighted to broaden the distribution of final scores. Historically, high improvement activities and Promoting Interoperability performance would make it difficult to distinguish scores because many participant's scores would be grouped in the upper quarter or even decile of the scoring range. We believe the proposed policy provides sufficient recognition for high-performing providers, especially since participants are evaluated relative to peers rather than against a predetermined performance threshold while also establishing a fairer basis for payment adjustments.

Comment: A few commenters supported the alternative using MIPS performance category weights in ASM, weighting all the four ASM performance categories. Additionally, a commenter suggested that both improvement activities and Promoting Interoperability performance categories should be weighted in alignment with MIPS policies to contribute positively to the overall score and offer opportunities for bonus points. A commenter also suggested CMS to more closely align the proposed ASM reweighting of the performance categories with MIPS policy. Another commenter encouraged CMS to align its scoring policies with traditional MIPS, APM Performance Pathway or MVP scoring policies.

Response: We recognize the commenters' desire for the ASM performance category weights and reweighting policy to match those used in MIPS. However, we believe the weights and corresponding

adjustments for the improvement activities ASM performance category better suit ASM's stated goal of integrating specialty managed care with primary care specialists. To incentive that integration, weighting the improvement activities ASM performance category higher than the Quality Payment Program's 15 percent weight as defined at § 414.1365(e)(1) is necessary. We also believe that our reweighting policy, though different from MIPS, meaningfully promotes the goals of the Promoting Interoperability category and aligns with CMS' broader efforts to move towards CEHRT adoption.[283] Though we appreciate the commenters' feedback that different reporting requirements for MIPS, APM Performance Pathway, MVP scoring policies and ASM may add additional reporting burdens, we believe it necessary to weight and measure as proposed to create sufficient performance and payment incentives to achieve ASM's objectives.

Comment: A few commenters did not support the proposed 20-point maximum negative adjustment for the improvement activities ASM performance category. The commenters expressed concerns that as proposed, the ASM scoring policies for the improvement activities performance category would be burdensome for specialists who would be required to enter into formal CCAs with a primary care physician and would act as a disproportionately punitive policy rather than one that encourages quality or performance improvement. A commenter expressed concern that the proposed scoring adjustment policy may indicate to clinicians that the improvement of activities performance category is not meaningful.

Response: We appreciate the comments regarding the proposed 20-point maximum negative adjustment for the improvement activities performance category under the ASM final scoring methodology. However, because participants are evaluated relative to their peers rather than against an arbitrary threshold, we disagree that this policy is punitive and believe that it encourages the increased engagement between PCPs and specialists that we seek to achieve through ASM. We refer readers to section III.C.2.d.(4) of this final rule for further discussion on the CCA requirements related to the improvement activities ASM performance category. We also note that the improvement activities maximum negative scoring adjustment of 20 points is larger in relative magnitude than in MIPS, in which the improvement activities score contributes 15 percent to the participant's final score as defined at

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[283] https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs.

§ 414.1365(e)(1). The larger magnitude of adjustment under ASM emphasizes the importance of improvement activities ASM performance category is to an ASM participant's successful performance.

Comment: A few commenters recommended that CMS adopt a policy allowing performance on improvement activities to contribute positively to the ASM final score.

Response: We recognize the commenters' concerns that the improvement activities ASM performance category does not yield a positive effect to the participant's final score. However, we disagree with the commenters that the negative scoring adjustment for the improvement activities category is appropriate for the model. We proposed applying weights only to the quality and cost categories, while scoring the improvement activities and Promoting Interoperability categories as negative scoring adjustments to broaden the distribution of final scores so that we could make more meaningful performance comparisons of ASM participants. If the improvement activities and Promoting Interoperability ASM performance categories were weighted similarly to MIPS, contributing only positively to the ASM final score, historically high performance in these categories would lead to clustering of final scores within a small range. By giving greater weight to the cost and quality ASM performance categories we can better differentiate performance and operationalize a wider range of payment adjustments.

Comment: A few commenters did not support the ASM final score proposal for calculating the ASM Promoting Interoperability negative adjustment and provided recommendations about scoring the Promoting Interoperability ASM performance category. A few commenters noted the ability to only earn points for cost and quality categories, interoperability measures at best maintain a neutral score and at worst a 20 percent reduction, indicating these measures are not valued. A commenter recommended that Promoting Interoperability ASM performance category should contribute positively to the final score. A commenter recommended adopting the threshold to 80 points to avoid a reduction and align with the 2026 IPPS Medicare Interoperability Program.

Response: We appreciate the commenters for their feedback. However, we disagree and believe that applying weights only to the quality and cost categories, while scoring the improvement activities and Promoting Interoperability categories as potential negative scoring adjustments creates the right incentives for ASM participants to meet these categories' requirements while allowing for meaningful

comparisons of performance. If the improvement activities and Promoting Interoperability categories were weighted similarly to MIPS, contributing only positively to the ASM final score, historically high performance in these categories would lead to clustering of final scores around a small range of final scores. By giving greater weight to the cost and quality performance categories we can better differentiate performance and operationalize a wider range of payment adjustments. We disagree that our scoring policy indicates that Promoting Interoperability is not valued. ASM participants would need to perform well on all ASM performance categories to receive high final scores. We appreciate the commenters for their proposed approach to scoring the Promoting Interoperability category with a threshold at 80 points. However, we disagree with the commenters because the Promoting Interoperability performance threshold of 80 points in the FY 2026 IPPS Medicare Interoperability Program (90 FR 37056) is designed with hospitals as the participants, not individual clinicians. Because a differentiation in participant performance is key to the successful implementation of ASM, a predetermined cutoff could potentially restrict the range of participant scores negating the intended effects of the negative scoring adjustments for the Promoting Interoperability ASM performance category.

After consideration of public comments, we are finalizing our proposed provisions on ASM performance category weights and scoring adjustments as proposed at § 512.745(a)(1).We did not receive specific comments on our proposed definition of "final score," so we are finalizing it as proposed at § 512.705.

(2) Requirements to Receive a Final Score

(a) Determining a Final Score When an ASM Participant Meets or Does Not Meet Minimum Data Submission Requirements

We proposed at § 512.745(a)(2) that we would determine whether an ASM participant is eligible to receive a final score for the applicable ASM performance year depending on the data submitted by the ASM participant. We proposed at § 512.745(a)(2)(i) that ASM participants who meet the data submission requirement for the quality ASM performance category as proposed at § 512.725(a)(1)(i) and receive quality and cost ASM performance category scores would receive a final score greater than zero but not exceeding 100 for the applicable ASM performance year. These ASM participants would receive a payment adjustment based on the methodology in section III.C.2.f of this final rule. We proposed at

§ 512.745(a)(2)(ii) that ASM participants who do not meet the data submission requirement for the quality ASM performance category as proposed at § 512.725(a)(1)(i) would receive a final score of zero for the applicable ASM performance year. As discussed in section III.C.2.f of this final rule, these ASM participants would be subject to the maximum negative payment adjustment for the applicable ASM payment year. We also note that an ASM participant's final score may also be affected if the ASM participant is affected by an eligible extreme and uncontrollable circumstance during an ASM performance year as discussed in section III.C.2.i of this final rule. We refer readers to section III.C.2.e.(2).(b) later in this section of this final rule for proposals related to final scores when ASM participants meet the quality ASM performance category data submission requirements but do not receive a quality or cost ASM performance category score. We also refer readers to Table B-D8 later in this section of this final rule for a summary of the proposed final score policies and their impact on payment adjustments.

As we proposed ASM to be a mandatory model, we believe that we must set a minimum data submission requirement for an ASM participant to meet or otherwise be subject to the maximum negative payment adjustment as discussed in section III.C.2.f of this final rule. We believe that our proposed minimum data submission requirement is reasonable because it requires that an ASM participant reports at least one non-administrative claims-based quality measure that also meets the data completeness requirement. Ultimately, this requirement would mean that the ASM participant is held accountable on the quality ASM performance category. Since we do not require ASM participants to submit data for the cost ASM performance category because we directly calculate the EBCMs, this proposed minimum data submission requirement would allow us to hold ASM participants accountable for quality and cost performance except in the case the ASM participant does not meet the case minimums for the quality and cost ASM performance category measures as discussed later in section III.C.2.e.(2).(b) of this final rule.

We solicited comments on our proposed requirements at § 512.745(a)(2)(i) to calculate a final score for ASM participants and our proposal at § 512.745(a)(2)(ii) that an ASM participant who does not meet these requirements would receive a final score of zero for the applicable ASM performance year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposal that ASM quality data is required for at least one quality measure for an ASM participant to receive a final score.

Response: We appreciate the commenter for their support of the proposal.

After consideration of public comments, we are finalizing at § 512.745(a)(2)(i) the requirements to receive a final score for ASM participants as proposed and we are finalizing at § 512.745(a)(2)(ii) our proposal that an ASM participant who does not meet these requirements would receive a final score of zero for the applicable ASM performance year as proposed.

(b) Not Determining a Final Score When an ASM Participant Cannot Be Scored on the Quality or Cost ASM Performance Category

At § 512.745(a)(2)(iii), we proposed that ASM participants who meet the data submission requirement for the quality ASM performance category as proposed at § 512.725(a)(1)(i) but do not receive a quality ASM performance category or a cost ASM performance category score would not receive a final score for the applicable ASM performance year. As discussed in section III.C.2.f.(4) of this final rule, these ASM participants would not receive payment adjustments in the corresponding ASM payment year. That is, only ASM participants who meet the requirements to receive a final score proposed earlier in this section of this final rule and receive a quality or cost ASM performance category score would receive a final score for the applicable ASM performance year. As proposed in section III.C.2.f.(4) of this final rule, ASM participants that receive a final score greater or equal to zero and not exceeding 100 would receive an ASM payment adjustment factor, defined in section III.C.2.f of this final rule, based on that final score for the applicable ASM payment year; otherwise, we proposed that the ASM participant would not receive a final score and would receive no payment adjustments for the applicable ASM payment year. We also refer readers to section III.C.2.i of this final rule for how the proposed extreme and uncontrollable circumstance policy influences an ASM participant's final score if an ASM participant has been deemed to be affected by an eligible circumstance.

We believe that it is appropriate to hold ASM participants accountable for quality and cost for the purpose of determining payment adjustments. We recognize that there may be instances where an ASM participant meets the minimum data submission requirements for the ASM performance category to receive a final score described earlier in this section of this final rule but does not meet the case

minimums for any required quality measure as discussed in section III.C.2.d.(2).(h) of this final rule or does not meet the case minimum for the required EBCM as discussed in section III.C.2.d.(3).(g) of this final rule. An ASM participant who does not receive a final score would receive a no payment adjustment (that is, neutral payment adjustment), meaning that they would not receive an upward or downward payment adjustment to their Medicare Part B payments for covered professional services for the applicable payment year because of participation in ASM. We believe that not determining a final score for the ASM participant and not adjusting payments during the applicable ASM payment year ensures that the ASM participant would not be unfairly penalized. We also believe that this proposal avoids complex reweighing policies. Reweighting policies would potentially mean that each final score represents a different mix of measures from different ASM performance categories. For example, one ASM participant could have a final score comprised of a cost ASM performance category score with improvement activities and Promoting Interoperability ASM performance category scoring adjustments whereas another could have a final score comprised of quality and cost ASM performance category scores. We believe that ensuring that all ASM participants' final scores reflect quality and cost performance is the most appropriate for determining payment adjustments that incentivize the care improvement and transformation that we seek to achieve through ASM.

We considered requiring that an ASM participant would only receive a final score if we could score them on all four proposed ASM performance categories as discussed in section III.C.2.d. of this final rule. We believed, however, that such a requirement would potentially be burdensome and not as well aligned with our intention to hold all ASM participants accountable for quality and cost performance at a minimum.

Table B-D8 summarizes the requirements to receive a final score and the resulting impact on payment adjustments discussed in this section and in section III.C.2.f of this final rule.

TABLE B-D8: FINAL SCORE POLICIES AND RESULTING PAYMENT ADJUSTMENTS

ASM Participant Meets Quality ASM Performance Category Data Submission Requirement?	ASM Participant Receives a Quality ASM Performance Category Score?	ASM Participant Receives a Cost ASM Performance Category Score?	Final Score	Payment Adjustment
Yes	Yes	Yes	Greater than 0 and not exceeding 100	Positive, neutral, or negative adjustment depending on final score
Yes	No	Yes	None	None (that is, neutral)
Yes	Yes	No	None	None (that is, neutral)
Yes	No	No	None	None (that is, neutral)
No	No	Yes	0	Negative adjustment equal to the applicable ASM risk level
No	No	No	0	Negative adjustment equal to the applicable ASM risk level

We sought comments on our proposal at § 512.745(a)(2)(iii) that ASM participants that we cannot score on the quality or cost ASM performance category would not receive a final score for an ASM performance year. We also sought comments on the alternative of requiring data submission for all four ASM performance categories that we considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support CMS' proposal to avoid reweighting and instead issue neutral payment adjustments in ASM when scores cannot be generated due to case minimums or data availability. The commenter expressed concern that while this approach may reduce administrative complexity, it would limit flexibility for ASM participants. The commenter recommended that CMS allow ASM participants the opportunity to supplement with available improvement activities or Promoting Interoperability ASM scores instead.

Response: We recognize the commenters' desire to promote flexibility by allowing improvement activities and Promoting Interoperability scores to supplement for when cost and quality ASM performance category scores are unavailable. However, based on historical MIPS performance in the improvement activities and Promoting Interoperability performance categories, we believe ASM participants would be likely to achieve higher ASM performance category scores in these two ASM performance categories. Therefore, scoring ASM participants only on improvement activities and Promoting Interoperability performance categories would lead to extremely high scores and not accurately reflect the complex and nuanced care delivered to ASM beneficiaries. We further stress that it is essential to score a participant on both cost and quality to adequately measure participant performance. Without those two ASM performance categories as discussed earlier in this section participants would not receive an ASM payment adjustment.

After consideration of public comments, we are finalizing at § 512.745(a)(2)(iii) our proposal that ASM participants that we cannot score on the quality or cost ASM performance category would not receive a final score for an ASM performance year as proposed.

(3) Complex Patient Scoring Adjustment

We proposed at § 512.745(a)(3) to apply a complex patient scoring adjustment to ASM participants' final scores for eligible ASM participants as described later in this section of this final rule. We proposed to use two risk indicators, Hierarchical Condition Category (HCC) risk scores and the proportion of patients with dual eligible status, "dual eligible proportion," to calculate the complex patient scoring adjustment to ASM participants' final scores. For the purposes of ASM, we proposed at § 512.705 that "risk indicator" refers to Hierarchical Condition Category (HCC) risk scores under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act or the proportion of beneficiaries with dual eligible status used in calculating the complex patient scoring adjustment as defined at § 512.745(a)(3).

Social and medical risk factors, such as income and co-occurring chronic conditions, play a major role in health status and, accordingly, the types of services and procedures furnished to a beneficiary. Physicians may face unique challenges delivering care to those with more "patient complexity," a term used to describe and account for a combination of factors that impact beneficiaries' health outcomes. In

ASM, our aim is to shift the focus away from volume and towards direct accountability for the cost and quality of health care services delivered. At the same time, by introducing an assessment of performance among physicians with similar clinical profiles but who may have different caseloads of complex patients, we seek to ensure that the care furnished by ASM participants is assessed fairly to espouse predictability and sustainability. We believe that inclusion of a complex patient scoring adjustment in the determination of final scores would help to achieve these objectives.

The Quality Payment Program calculates a complex patient bonus and adds it to the MIPS final score for qualifying MIPS eligible clinicians based on their caseload of complex patients using two well-established risk indicators within the Medicare program: HCC risk scores and dual-eligible proportion under § 414.1380(c)(3). The CY 2018 Quality Payment Program final rule established a complex patient bonus to be added to the final score for the CY 2020 MIPS payment year (82 FR 53771 through 537756) as required by MACRA. The purpose of the policy was to address the impact patient complexity may have on MIPS scoring and mitigate discrepancies without masking performance. Subsequent rulemaking continued using the complex patient bonus and modified the formula based on several factors including interested parties feedback, updated analysis, and implications from the HHS Assistant Secretary for Planning and Evaluation (ASPE) reports to Congress (86 FR 65510 through 65519).

We considered, but did not propose, adopting an approach in which quality performance is risk adjusted for complex patients. We believe that providers have substantial control over the health care encounter and the outcomes assessed after the encounter. Thus, we decided that adjustments made at the quality measure or quality ASM performance category level would undermine our core aim to promote direct accountability and high-quality outcomes for all beneficiaries. Further, ASPE's second report released in June 2020, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, provides recommendations for addressing risk factors in Medicare's value-based payment programs, including discouraging risk adjustments on measures that assess the process and outcome of care given in the care setting.[284] The report reasoned that adjusting quality measures may have a negative impact on transparency for consumers and may inadvertently lower the standard of care. Instead, the report suggests

[284] https://aspe.hhs.gov/sites/default/files/private/pdf/263676/Social-Risk-in-Medicare%25E2%2580%2599s-VBP-2nd-Report-Executive-Summary.pdf.

including additional payments or bonuses for practices with a greater share of dual eligible and high-risk patients is more appropriate as it recognizes that providing excellent care for complex beneficiaries may require more physician services, resources, and capacity.[285]

Since the goal of the complex patient scoring adjustment policy in ASM is: (1) to protect access to care for complex patients and provide them with excellent whole-person care; and (2) to avoid placing ASM participants who care for complex patients at a potential disadvantage, we believe applying this complex patient scoring adjustment to the final score to determine payment adjustments is appropriate because caring for complex patients can affect all aspects of a practice, not just success in specific ASM performance categories. However, we recognize the importance of holding providers accountable for overall results, regardless of social and medical risk, and would want ASM participants to know the contribution of the complex patient scoring adjustment, if applicable, to their final score. Therefore, an ASM performance report, as discussed later in this section of this final rule, would include an ASM participant's complex patient scoring adjustment, if applicable, in addition to their final scores to ensure transparency in final score calculations.

We proposed at § 512.745(a)(3)(i) that ASM participants who have at least one risk indicator (HCC risk scores and dual proportion) that is equal to or greater than the reference median for the risk indicator, described later in this section, for an applicable ASM performance year would have the complex patient scoring adjustment added to their final score for a given ASM performance year. The complex patient scoring adjustment would only be provided if the ASM participant meets the requirements to receive a final score greater than zero proposed at § 512.745(a)(2)(i) and discussed in section III.C.2.e.(2). of this final rule. We note that the proposed complex patient scoring adjustment calculation methodology is similar to MIPS' complex patient bonus. However, we proposed limited methodological adjustments to better align the scoring adjustment with ASM's scoring approach.

To determine whether an ASM participant would qualify for the complex patient scoring adjustment, we proposed to calculate a reference median for each risk indicator (HCC risk score and dual proportion) for each ASM cohort and for each ASM performance year. We proposed to calculate the

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[285] https://aspe.hhs.gov/sites/default/files/private/pdf/263676/Social-Risk-in-Medicare%25E2%2580%2599s-VBP-2nd-Report-Executive-Summary.pdf.

reference median of the ASM cohort's HCC risk scores and dual proportions using applicable data from 1 calendar year prior to the start of the applicable ASM performance year. We would only use applicable data from ASM participants that meet the data submission requirements for the quality ASM performance category for the applicable ASM performance year as described at § 512.725(a)(1)(i). For example, we would calculate the reference medians for the 2027 ASM performance year using data from the 2026 calendar year. We would then calculate each risk indicator (HCC risk score and dual proportion) for each ASM participant using data from the current ASM performance year (in this example, the 2027 ASM performance year). ASM participants who have at least one calculated risk indicator for the ASM performance year that is equal to or greater than the reference median risk indicator calculated for their applicable ASM cohort would be eligible to receive the complex patient scoring adjustment. ASM participants that do not have data available to calculate either risk indicator score for an applicable ASM performance year would not be eligible to have the complex patient scoring adjustment added to their final score.

We also proposed to determine the reference median of each risk indicator separately for each ASM cohort to align with our proposed approach to make separate performance comparisons within each of these participant cohorts. We considered determining the reference median for each risk indicator using data from data from the concurrent ASM performance year but were concerned that Medicare claims runout periods would not provide complete data to calculate these medians within an ASM performance year. This approach would mirror the method that MIPS uses in calculating the complex patient bonus under § 414.1380(c)(3) with adaptations to align with the overall performance comparison approach of ASM. We also considered not requiring that an ASM participant have a median or higher value for at least one of the two risk indicators to qualify for the complex patient scoring adjustment. While this alternative would expand the number of ASM participants that would qualify for the complex patient scoring adjustment for an ASM performance, we believe targeting the complex patient scoring adjustments to ASM participants treating a higher caseload of highly complex patients would be more appropriate. We also considered using the mean, instead of the proposed median of the risk indicator as the cutoff point but believe it could decrease the percentage of ASM participants that would receive the

complex patient scoring adjustment like what was observed by the Quality Payment Program in exploratory analyses for the MIPS complex patient bonus methodology (86 FR 65110).

We proposed at § 512.745(a)(3)(ii)(C), like in MIPS, to determine a standardized score for each risk indicator based on the mean and standard deviation of the raw risk indicator score to provide a standardized measurement of the distance between each risk score and the mean: (raw risk indicator score−risk indicator mean)/risk indicator standard deviation. We proposed to use the mean and standard deviation from 1 calendar year prior to the ASM performance year using applicable data from ASM participants identified for that ASM performance year. Standardization allows us to determine how far each risk indicator score is from the mean. For example, the mean and standard deviations for the 2027 ASM performance year would be determined based on data from CY 2026 for ASM participants identified for the 2027 ASM performance year, which is a similar methodology to our proposed methodology to calculate the risk indicator reference medians described earlier in this section of this final rule.

We proposed at § 512.745(a)(3)(ii)(A) to calculate the social complex patient scoring adjustment component as follows:

Medically complex patient scoring adjustment component = 1.5 + 4*associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by an ASM participant.

We proposed at § 512.745(a)(3)(ii)(B) to calculate the medical complex patient scoring adjustment component as follows:

Social complex patient scoring adjustment component =1.5 + 4* associated with dual proportion standardized score.

We proposed § 512.745(a)(3)(ii)(C) to add the components together to calculate one overall complex patient scoring adjustment.

We proposed at § 512.745(a)(3)(iii) that ASM participants with an HCC risk score or dual-eligible proportion above their respective medians, as calculated earlier in this section, would receive a complex patient scoring adjustment that cannot exceed 10 points and cannot be below zero points. We

considered a complex scoring patient adjustment that could exceed 10 points and a complex scoring adjustment with a maximum point value less than 10 points but not below zero points. However, we believe that aligning the proposed complex patient scoring adjustment maximum point value with the MIPS complex patient bonus maximum point value would reduce confusion across ASM participant who would have previously participated in MIPS.

We believe the proposed formula compensates for a potential difference in payment related to HCC risk scores and dual proportion since MIPS uses the same approach in calculating the MIPS complex patient bonus defined at § 414.1380(c)(3) (86 FR 65510 through 65519). We believe this methodology and formula are strongly supported by data and analyses explained in the CY 2022 PFS proposed rule (86 FR 65510 through 65519). Furthermore, dual enrollees tend to have lower income, a greater prevalence of mental health conditions, somatic chronic conditions, and significantly higher annual costs of care than their nondual counterparts.[286] Thus, we believe that a complex patient scoring adjustment based on HCC risk scores and dual proportions, as is done in MIPS, would not only reduce inappropriate penalties among ASM participants that disproportionately care for dual eligible, high-risk populations but would also reduce inappropriate payments for ASM participants that care for less complex populations.

We solicited comments on the proposed inclusion of the complex patient scoring adjustment in final scores and the proposed methodology for calculating the complex patient scoring adjustment. We also sought comments on our alternatives considered related to calculating the reference median based on data from the concurrent ASM performance year and using a reference mean instead of a reference median. We also sought comment on the alternative of not requiring ASM participants to have at least one risk indicator that is equal to or greater than the reference median to receive the complex patient scoring adjustment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed use of a complex patient scoring

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[286] Johnston KJ, Joynt Maddox KE. The Role Of Social, Cognitive, and Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Aff (Millwood)*. 2019;38(4):569-576. doi:10.1377/hlthaff.2018.05032. https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05032.

adjustment as it helps ensure that clinicians are not inadvertently penalized for treating medically or socially complex populations. Additionally, a commenter noted that Medicare Advantage also uses HCC coding and risk adjustment to account for the higher costs associated with complex patients. A commenter explicitly supported the use of a cohort median as the basis for the complex patient scoring adjustment but also recommended that CMS monitor the results of each ASM cohort to ensure that the complex patient scoring adjustment is properly sized. Similarly, another commenter also noted that CMS must maintain the correct balance between supporting ASM participants and ensuring all participants have a fair chance to achieve a positive ASM payment adjustment.

Response: We appreciate the commenters for their support of the proposal. We agree that complex patient adjustment helps ensure that ASM participants are not penalized for providing care for medically or socially complex beneficiaries. We appreciate the commenters for their support of the median as the basis for determining a complex patient scoring adjustment. We will monitor participant results to ensure the adjustment is appropriately sized and changes are needed, will address those changes in future notice-and-comment rulemaking. Lastly, we believe that as currently proposed the complex patient scoring adjustment strikes the right balance of supporting participants facing unique challenges while also maintaining a scoring system that recognizes high performance.

Comment: Several commenters noted limitations with the proposed complex patient scoring adjustment. A few commenters noted that HCC codes do not appropriately capture the severity of illness, particularly for pain, and that HCC risk scores are designed for predicting cost and utilization across broad medical conditions not the conditions in the ASM cohort. A few commenters noted that dual-eligible proportion is a useful proxy for socioeconomic risk but does not differentiate between patients with complex pain syndromes and those with other chronic conditions. A commenter expressed concern that calculating a standardized score based on mean and standard deviation may dilute the impact of truly complex pain patients, especially in specialty practices where pain-related complexity is common but not well-coded. Another commenter expressed concern that applying the complex patient scoring adjustment to those above the median for the risk indicator may exclude those serving moderately complex populations who also experience care management burden. Another commenter shared their belief that because the complex patient scoring adjustment is applied to the ASM final score, and not to each

performance category, clinicians whose quality or cost performance is negatively impacted by patient complexity may still be at risk. A commenter expressed concern on whether a 10-point cap is a sufficient adjustment if the cost performance category has a weight of 50 percent. Additionally, a few commenters recommended that the risk adjustment should account for patient complexity and co-morbidities.

Response: We appreciate the commenters' feedback, but we disagree with their perspective that the complex patient scoring adjustment is limited in its measurement of medically or socially complex beneficiaries. Even though HCC codes do not directly capture beneficiary pain, they do capture relative severity and comorbidities including many conditions relevant to pain. We believe in using HCCs because it is consistent, auditable and resistant to subjective interpretation as compared to ad-hoc clinical judgments on pain levels. We agree with the commenters that the rate of dual-eligible proportion is a useful proxy for socioeconomic risk, yet we note that the rate of dual-eligible proportion is not meant to capture the nuances between patients with complex pain syndromes and those with chronic conditions. The HCC score best addresses those factors as well as patient complexity and co-morbidities. Standardizing scores for each risk indicator based on the mean and standard deviation of the raw risk indicator scores is a standard statistical method to ensure comparability across participants and specialties. We do not believe standardizing scores dilutes complex patients, rather it normalizes variation so that providers are not unfairly advantaged or disadvantaged by the differences in coding practices like, for example, in specialty practices where pain related complexity is common. Awarding the complex patient scoring adjustment to participants whose risk indicator is equal or greater than the reference median ensures the bonus awards clinicians facing significant care management burden. If we were to award the complex patient scoring adjustment to everyone, or expand the cap beyond 10 points, we could potentially weaken the ASM incentive structure and begin to blur meaningful differences in performance. We also believe that aligning the proposed complex patient scoring adjustment maximum point value with the MIPS complex patient scoring adjustment maximum point value would reduce confusion for ASM participants who may previously have participated in MIPS. It is also important to note that the ASM cost performance category includes a sophisticated risk adjustment methodology meant to address the commenters exact concerns as described in III.C.2.d.(3) of the final rule. The Risk Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure (MIPS Q492) also

includes a risk-adjustment process to account for clinical variables and social risk factors.

Comment: Several commenters offered recommendations to address the limitations in the proposed complex patient scoring adjustment. Recommendations include: expanding the methodology to include additional risk factors, adding a variety of clinical modifiers/markers and functional status to the risk adjustments, excluding New York Heart Association (NYHA) stage D patients from the analysis, adding a mechanism to identify when ASM participants treat chronic medical conditions, such as recognizing an add-on complexity code like G2211 or a quantity or variety of CPT codes, and incentivizing pain ASM participants who drive the Improvement Activities. A few commenters suggested adding 10 or 15 performance add-on points for clinicians practicing in challenged economic areas, such as those with a high score in the area deprivation index while another commenter suggested providing bonus points or favorable benchmarks for ASM participants serving high-risk populations. A commenter recommended specialty-specific risk adjustment, noting that interventional pain care involves unique clinical burdens that are not often captured by general medical risk models. Additionally, the commenter recommended that CMS engage with specialists to ensure scoring adjustment aligns with the realities of clinician practices and does not inadvertently penalize high-quality care.

Response: We appreciate the commenters' recommendations on possible adjustments to the complex patient scoring adjustment. However, we disagree because at a high level, we wanted to align the complex patient scoring adjustment in ASM with the complex patient bonus policy in MIPS to reduce confusion for participants who have previously participated in MIPS. Though we did not consider the recommendations referenced within these comments, if we did, we would do so in future notice-and-comment rulemaking. We also appreciate the commenters for expressing their concerns that the complex patient scoring adjustment may inadvertently penalize participants providing high-quality care. However, the magnitude of the complex patient scoring adjustment was set to reward beneficiaries facing unique challenges, but it is capped to maintain appropriate scoring rewards for ASM participants providing high-value care. We will monitor ASM participants' final scores, the adequacy of the complex patient scoring adjustment, and will address any possible refinements to the adjustment in future notice-and-comment rulemaking.

Comment: Several commenters recommended the need for a robust risk adjustment without

discussing the complex patient score adjustment specifically. The commenters expressed concern that safety net providers and other ASM participants who treat complex and underserved populations may be disadvantaged. A few commenters also expressed concern that the lack of a robust adjustment could lead to unintended consequences, such as under-reimbursement for high-value services, disincentives to serve complex Medicare patients, or reduced access to care for vulnerable patients. A commenter expressed concern that the one-size-fits all design of ASM does not reflect material differences between community practices and tertiary referral centers and that the current methodology offers limited protection for rare, appropriate, high-cost care. Another commenter noted that ASM participants in low-income communities have compounded costs and pressures to meet more than just primary care needs. Another commenter suggested using patient-centered outcomes that reflect patient goals and value, not just cost metrics.

Response: We appreciate the recommendations to further enhance risk adjustment and strengthen support for safety net providers. It is important to note that the EBCM methodology used to determine the cost ASM performance category score utilizes a sophisticated risk adjustment methodology that benefits safety net providers and other ASM participants treating complex and underserved populations. Coupled with the complex patient scoring adjustment, we believe our policies as proposed sufficiently recognize the challenges facing safety-net providers and would not inherently lead to reduced access to care for vulnerable patients. We would not expect to identify ASM participants that furnish most of their services in tertiary referral centers because of our ASM participant eligibility criteria; we refer readers to section III.C.2.c.(3) of this final rule for further discussion. Although we did not consider scoring community practices differently, if we did, we would do so in future notice-and-comment rulemaking. Separately, we would also like to note two points. First, we, like the commenters, understand that ASM participants in low-income communities face different pressures than those in higher-income communities. For these reasons, we proposed that the complex patient scoring adjustment utilizes the proportion of patients with dual eligible status in the adjustment's calculation. The link between dual eligible status and income level is well documented and researched.[287] Second, we refer commenters to the quality ASM performance category discussion in section III.C.2.d.(2) of this final rule which includes measures like the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) which, as a patient-reported

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[287] https://www.kff.org/medicare/a-profile-of-medicare-medicaid-enrollees-dual-eligibles.

outcome measure, tracks changes in a patient's reported functional status over time.

Comment: A commenter expressed concern that ASM may encourage specialists to seek care for low acuity patients who can be managed by a primary care practice, noting those beneficiaries are likely to score well on most of the model's quality and episode cost measures. The commenter also noted that earlier stage low back pain and congestive heart failure are not currently included in Medicare Advantage risk adjustment models.

Response: We appreciate the commenter for their feedback. We disagree that ASM may encourage specialists to seek out care for low acuity patients because the EBCM's risk adjustment process and will not sufficiently reward participants for seeking out low acuity patients. We also see value in ASMs longitudinal care approach to patients with chronic conditions. Providing early, preventive care to low acuity patients should result in better health outcomes and reduce beneficiary expenditures to prevent those patients falling into a higher acuity status.

Comment: A few commenters expressed concerns about fairly measuring performance of ASM participants when providing care to high-need patients. A commenter expressed concern with how specialists will be attributed in complex cases when multiple clinicians are involved. A commenter recommended comprehensive risk adjustment to mitigate potential risks associated with treating high-need patients.

Response: We appreciate commenters for raising these concerns. We note that the complex patient scoring adjustments would help increase the final scores of qualifying ASM participants as it acknowledges the challenges in providing care to high-needs patients, which may result in lower performance in some ASM performance categories. We refer commenters to the EBCM methodology in sections III.C.2.d.(3)(b) and III.C.2.d.(3)(c) of this final rule which detail how episodes are attributed, even in complex cases. As we have stated throughout this section of this final rule, we believe that measure-specific risk adjustment coupled with the complex patient scoring adjustment provides a simple but comprehensive risk adjustment approach to increase final scores and the likelihood for a more favorable payment adjustment for qualifying ASM participants.

After consideration of public comments, we are finalizing the proposed complex patient scoring adjustment provisions at § 512.745(a)(3).

We did not receive public comments on the proposed definitions of "dual eligible proportion," and "risk indicator" at § 512.705 and therefore, we are finalizing as proposed

(4) Small Practice Scoring Adjustment

We proposed at § 512.745(a)(4) that an ASM participant would be eligible to receive a small practice scoring adjustment in the calculation of their final score. We proposed at § 512.705 to define a "small practice" as a practice consisting of 15 or fewer clinicians at the time we identify ASM participants for an ASM performance year as described at § 512.710(g). We proposed at § 512.705 to define a "solo practitioner" as a practice consisting of 1 clinician at the time we identify ASM participants for an ASM performance year as described at § 512.710(g). Our proposed definitions for small practice and solo practitioner align with MIPS' small practice definition at § 414.1305.

We proposed at § 512.745(a)(4)(i) to add 10 points to the final score of an ASM participant who: (1) is in a small practice as defined at § 512.705; (2) is not a solo practitioner as defined at § 512.705; and (3) and meets the requirement to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year. We proposed at § 512.745(a)(4)(ii) to add 15 points to the final score of an ASM participant who is a solo practitioner as defined at § 512.705 and meets the requirement to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year.

We believe that it is necessary to support ASM participants against the potential challenges that they face in participation in Innovation Center models and other CMS value-based payment programs, like the Quality Payment Program. Participants in MIPS have provided feedback that many small practices and solo practitioners face challenges in their ability to participate in MIPS, including the costs to implement and maintain CEHRT, staff and training costs, and limited staff capacity to manage the complexity of the program (89 FR 98452). MIPS has several policies that aim to support small and solo practices, including scoring and reweighting policies as defined at § 414.1380. We considered adopting some of these policies for the purposes of ASM given our use of the MVPs as a framework for this model. However, our goal in designing a scoring policy for ASM was to increase incentives for participation and to reduce the complexity of reweighting policies based on the characteristics of an ASM participant or the context in which they practice.

We analyzed historical MIPS final score performance among a pool of likely ASM participants for both heart failure and low back pain. We found that small practices, including solo practitioners, were more likely to receive lower final MIPS scores compared to MIPS eligible clinicians in larger practices (that is, TINs with more than 15 clinicians). We also found that solo practitioners were more likely to receive lower scores than MIPS eligible clinicians in small practices (that is, practices with 2 to 15 clinicians in this situation). For these reasons, we believe that ASM participants in small practices would likely score lower than their counterparts in larger practices under ASM, with solo practitioners potentially scoring lower than other small practices. While we would not want to inadvertently skew the distribution of ASM participant final scores, we believe that it would be appropriate to support ASM participants in small practices to receive a final score adjustment.

We based the proposed magnitudes of the final scoring adjustments based on the distribution of MIPS final scores among likely ASM participants. We also considered small practice scoring adjustments that were lower and higher than the proposed 10 points for non-solo practitioner ASM participants in small practices and 15 points for solo practitioner ASM participants. However, we believe that the proposed magnitudes of the scoring adjustments would appropriately increase the applicable ASM participants' score and would be easily understood by ASM participants. We refer readers to section III.C.2.f.(4).(b) of this final rule for an alternative level of risk that we considered for ASM participants in small practices.

We believe that using a flat adjustment on the final score would be a clear and transparent method to support ASM participants to increase their score relative to other ASM participants so as to avoid potentially creating a barrier for them to achieve a net positive payment adjustment (see section III.C.2.f in this final rule for further discussion on our proposed payment methodology). Since we did not propose to reweight ASM performance categories in the calculation of final scores as discussed earlier in this section of this proposed rule to simplify the data submission requirements and scoring policies, we believe that a flat adjustment would be a simple but effective mechanism to support ASM participants in small practices.

We considered but did not propose a similar flat-point adjustment for ASM participants in rural areas as defined at § 512.705 (which aligns with the MIPS rural area definition at § 414.1305). We,

however, found in our analysis of historical MIPS performance data among likely ASM participants that there was not a systematic difference in the performance data between likely ASM participants in rural and non-rural areas. While MIPS reduces the reporting requirements for the improvement activities performance category for MIPS eligible clinicians in rural areas as defined at § 414.1380(b)(3), the lack of a systematic difference in historical MIPS performance between likely ASM participants of rural and non-rural status led us to not propose a scoring adjustment for ASM participants in rural areas. Furthermore, we observed that a high proportion of likely ASM participants in small practices were in rural areas. Adding a rural scoring adjustment on top of the small practice scoring adjustments would potentially be duplicative and inappropriately skew the distribution of final scores.

We solicited comments on our proposal at § 512.745 (a)(4)(i) to add 10 points to the final score of an ASM participant who is in a small practice, is not a solo practitioner, and meets the requirements to receive a final score greater than zero and not exceeding 100. We also sought comment on our proposal at § 512.745 (a)(4)(ii) to add 15 points to the final score of an ASM participant who is a solo practitioner and meets the requirements to receive a final score greater than zero and not exceeding 100. Finally, we sought comments on the alternative we considered of applying a similar flat-point adjustment for ASM participants in rural areas.

We received public comments on these proposals. The following is a summary of the comments we received related to the small practice scoring adjustment and solo practice scoring adjustment.

Comment: Several commenters supported the proposed small practice scoring adjustment of 10 points for small practices that are not solo practitioners and meets the requirement to receive a final score greater than zero and a 15-point scoring adjustment for solo practitioners that meets the requirement to receive a final score greater than zero. Commenters noted this is a simple, transparent approach and an appropriate, fair compromise for known disparities in reporting infrastructure, staffing, and capacity. A commenter supported the proposal but requested CMS to closely monitor the results of each cohort in the ASM to ensure that the small practice scoring adjustment is properly sized so that ASM participants from small practices are not unfairly punished or rewarded.

Response: We appreciate commenters for their support of this proposal. We agree that the small practice scoring adjustment is a simple approach to support practices that face additional burdens in

Innovation Center models. We will monitor the results of these cohorts to identify if any refinements to the small practice scoring adjustments would be justified.

Comment: A few commenters supported the proposed small practice scoring adjustment contingent on CMS adoption a group practice participation option. Some of the commenters noted that because ASM is proposed as an individual clinician model, every ASM participant is performing as a solo practitioner relative to reporting burden, performance management, and financial impact.

Response: We appreciate the commenters' feedback, but we disagree that the small practice scoring adjustment should be contingent on CMS adopting a group practice participation option. The ASM small practice scoring adjustment reflects the reality that small and solo practitioners face challenges in their ability to participate in historical programs like MIPS which include costs to implement and maintain CEHRT, staff and training costs and a more limited staff capacity (89 FR 98452). These challenges and burdens persist regardless of the ASM participation level set by CMS. Even though the ASM participants are individual providers, providers practicing in a larger group still have access to reporting structures and support unavailable to providers in smaller groups.

Comment: Several commenters expressed concern that small practices would still be disproportionately harmed by ASM. The commenters expressed concern that solo practices may be less likely to engage or may have lower scores due to limited resources and the requirements of the model and that the proposed small practice scoring adjustment is not sufficient to offset the burden and cost associated with the model. A few commenters stated their belief that small practices typically do not have the staff and resources to compete with larger practices and may divert resources away from small and rural practices. A few commenters requested CMS provide resources and technical assistance to enable small practices to transition to value-based care. Another commenter requested that CMS ensure that ASM participants are not penalized for a lack of infrastructure prior to the model.

Response: We appreciate the commenters' feedback but believe that our small practice scoring adjustment, our finalized provision in section III.C.2.d.(1).(b) of this final rule to allow for small practice TIN level quality ASM performance category reporting, and the length of time participants have to prepare for ASM appropriately accounts for the burdens small practices face. The 10/15 point small/solo provider scoring adjustments provides ASM participants with the recognition of their hardships without

undermining their incentives to pursue meaningful performance improvement. Our finalized provision in section III.C.2.d.(1).(b) of this final rule to allow for group reporting of the quality ASM performance category for small practices and group reporting for the improvement activities and Promoting Interoperability ASM performance categories for all participants should ease smaller practice burden in meeting the requirements of these performance categories. To assist providers to be ready for ASM's requirements by the model start, we plan to share educational resources with eligible ASM participants beginning in 2026. Additionally, launching the model in 2027, though announced in 2025, gives appropriate time for ASM participants, from both large but especially smaller practices, to begin adopting the right infrastructure to participate in the model. For the reasons provided we do not believe it necessary to exempt providers in small practices from ASM.

Comment: A commenter suggested that policy flexibilities or exemptions from mandatory reporting should be extended to small practices. Additionally, a commenter suggested that benchmarks should be adjusted for smaller practices in an effort to reduce financial risk.

Response: We appreciate these commenters for their suggestions to address the challenges faced by small practices. Our finalized provision in section III.C.d.(1).)(b) of this final rule allows for small practice to report quality measures in the quality ASM performance category at the TIN level. However, we did not consider exemptions from mandatory reporting for small practices because ASM is designed to ensure that all participants are evaluated. Exemptions would create gaps in measurement that could reduce the integrity of the model. We also did not consider adjusting benchmarks for the realities faced by smaller practices because as discussed earlier in this section, we believe that the small practice scoring adjustment, and our finalized provision to ease quality reporting burden for ASM participants in small practices would account for those challenges in a simpler and more transparent way. Lastly, the small practice scoring adjustment automatically raises the participant's final score, helping them achieve a higher score and therefore lowering small practices' financial risk.

Comment: A commenter agreed with the proposed approach CMS is taking in applying a scoring adjustment for those who are participating in small practices but expressed concern that the continued relaxation of CEHRT use requirements will only isolate smaller practices from benefiting from interoperability. The commenter recommended providing more incentive-based approaches for those who

are solo practitioners or small practices and perhaps promoting the adoption of certified technology, while not requiring full Base CEHRT, may be a way to bring these practices into the current environment of an interoperable network.

Response: We appreciate the commenter for their recommendation. However, we disagree and note that small practices are not exempt from the CEHRT requirement within the Promoting Interoperability performance category. The small practice scoring adjustment is awarded regardless of a small practice's performance on the Promoting Interoperability performance category and may help provide additional support for infrastructure investments such as CEHRT. We may consider the exploration of additional incentives or support for small practices in the future.

We also solicited comments on an alternative where a similar flat-point adjustment would be applied for ASM participants in rural areas.

Comment: A few commenters supported the alternative considered to use ASM rural scoring adjustment, a scoring adjustment for ASM participants in rural areas, similar to the small practice scoring adjustment. A commenter expressed support for ASM rural adjustment, noting unique challenges, such as limited funding for technology upgrades, insufficient staff for reporting requirements, barriers to interoperable systems and the ASM requirement for individual rather than group reporting. Another commenter expressed support for ASM rural scoring adjustment, noting that rural physicians treating patients with low back pain often encounter individuals with limited access to care management and first-line treatments, as well as complex needs that require more time to address.

Response: We appreciate commenters for their feedback. Although we considered implementing a rural scoring adjustment we found in our analysis of historical MIPS performance data among likely ASM participants that there were no systematic differences in the performance data between likely ASM participants in rural and non-rural areas. We believe that the small and solo practice scoring adjustments support ASM participants in smaller practices directly by addressing participation barriers without undermining incentives for ASM participants in large rural systems to improve.

Comment: A few commenters supported and provided recommendations on the alternative approach to have a rural scoring adjustment, a scoring adjustment for ASM participants in rural areas, similar to the small practice scoring adjustment. A commenter acknowledged CMS rationale for not

including a rural adjustment but recommended that CMS monitor performance by geographic location and implement significant geographic adjustments to ensure rural practices are not disproportionately harmed and to account for rural healthcare challenges. Another commenter recommended that CMS provide technical assistance for ASM participants in rural areas and implement protection for clinicians in rural areas, including a differential penalty structure, considering specific quality measures to reflect unique care delivery patterns, such as stabilization and transfer protocols.

Response: We appreciate commenters for their feedback. As previously discussed in this section of this final rule, we considered implementing a rural scoring adjustment but did not find evidence of differences in historical performance between likely ASM participants in rural versus non-rural areas. We will continue to monitor performance and final scores by geographic location. If systematic differences in final scores were to arise, we could consider additional provisions to address these differences in future notice-and-comment rulemaking. To help providers in rural areas with technical assistance, we plan to provide educational materials to eligible ASM participants beginning in CY 2026. We did not consider protections for clinicians in rural areas because ASM is designed to ensure that all participants are evaluated under a consistent framework. Exemptions would create gaps in measurement that could reduce the integrity of the model. As noted earlier in this section of this final rule, we also expect a high degree of overlap between ASM participants in rural areas in small practices based on historical MIPS performance data we analyzed, meaning that we believe that many rural practices would be eligible for the small practice scoring adjustment.

After consideration of public comments, we are finalizing our proposed definition of "small practice" and "solo practitioner" as proposed at § 512.705. We are also finalizing at § 512.745(a)(4)(i) to add 10 points to the final score of an ASM participant who is in a small practice, is not a solo practitioner, and meets the requirements to receive a final score greater than zero and not exceeding 100 as proposed. We are also finalizing at § 512.745(a)(4)(ii) to add 15 points to the final score of an ASM participant who is a solo practitioner and meets the requirements to receive a final score greater than zero and not exceeding 100 as proposed.

(5) Final Score Calculation

We proposed at § 512.745(a)(5) the following formula to calculate the final score for each ASM participant that meets the minimum data submission requirements discussed in section III.C.2.e.(2).(a) of this final rule:

> Final score = [(quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + Complex Patient scoring adjustment + Small Practice scoring adjustment.
>
> Note: The final score cannot be below zero points or exceed 100 points

We believe that this proposed final score calculation appropriately utilizes the quality and cost ASM performance category scores as outlined in sections III.C.2.e of this final rule, weights the quality and cost ASM performance categories, and considers the inclusion of the negative improvement activities ASM performance category scoring adjustment, the negative Promoting Interoperability ASM performance category scoring adjustment, the positive complex patient payment adjustment, and positive small practice scoring adjustment.

For example, under the proposed final score calculation and the proposed weights for the quality and cost performance category, if an ASM participant has a quality performance category score of 80 percentage points [(40 measure achievement points out of 50 available measure achievement points)], a cost performance category score of 75 percentage points [(7.5 achievement points out of 10 available achievement points)], a negative improvement activities performance category scoring adjustment of -10 from successfully attesting to one improvement activity, a negative Promoting Interoperability ASM performance category scoring adjustment of -2.7 ((100 potential maximum Promoting Interoperability ASM performance category points – 73 Promoting Interoperability ASM performance category score)/-10), a complex patient scoring adjustment of 5.5, and a small practice scoring adjustment of 10 from being in a small practice, the final score would be as follows:

> Final Score = [0.80 × 50 percent) + (0.75 × 50 percent)] × 100 + (-10) + (-2.7) + 5.5 + 10 = 80.3.

The ASM participant under the example conditions described above would have 77.5 points from the quality and cost ASM performance categories ([(0.80 × 50 percent) + (0.75 × 50 percent)] × 100), before the scoring adjustments are applied, and a final ASM score of 80.3 points

We solicited comments on the proposed final score calculation formula.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed ASM final score formula. A commenter agreed with CMS that the final score could provide a broader range of scores and outcome distributions. A commenter acknowledged the changes in ASM from MIPS scoring and recommended that CMS closely monitor these changes to ensure there is not a recurring issue with edge cases in the ASM cohort.

Response: We appreciate the commenters for their support of the proposal. We agree that the ASM final score formula will provide a broad range of scores and outcome distributions. We will monitor scoring results and address any needs for refinements in future notice-and-comment rulemaking.

Comment: A few commenters recommended that CMS provide additional clarity, safeguards, and simplification of the proposed ASM final score formula. A commenter suggested adding reliability and volume safeguards, such as reweighting when measure reliability or case counts are low, and recommended more details on the proposed formulas, benchmarks, and reference populations. Another commenter suggested that CMS to significantly simplify the proposed final score formula before ASM is finalized, noting that many healthcare organizations already struggle to follow requirements for existing programs.

Response: We appreciate commenters for feedback on the final score calculation formula. However, we believe that as proposed in section III.C.2.e.(5) of the final rule, the final score formula is as simple as possible while appropriately utilizing the quality and cost ASM performance category scores as outlined in sections III.C.2.e of this final rule, weights the quality and cost ASM performance categories, and considers the inclusion of the negative improvement activities ASM performance category scoring adjustment, the negative Promoting Interoperability ASM performance category scoring adjustment, the positive complex patient payment adjustment, and positive small practice scoring adjustment. To help healthcare organizations who may struggle to follow ASM requirements and scoring policies, we plan to release educational materials beginning in CY 2026. We note that many of ASM's scoring requirements, including both the cost and quality performance categories as discussed in sections III.C.2.d.(3).(f) and III.C.2.d.(2).(h).(ii) of the final rule respectively, require minimum volumes to be scored. We will also release benchmark ranges, reference populations, and formulas as they become finalized in each ASM

performance year in a form and manner determined by CMS.

Comment: A commenter expressed concern that the proposed ASM scoring methodology does not adequately adjust for ASM participants treating patients with high clinical severity, such as frailty, device dependence, transplant candidacy, and multi-organ comorbidity. The commenter shared their belief that the proposed scoring methodology puts too much emphasis on cost without appropriately balancing the value of advanced therapies.

Response: We appreciate the commenters' feedback, but we believe the ASM scoring methodology as proposed in section III.C.2.e.(5) of the final rule is inclusive of the factors mentioned in the comment. The complex patient scoring adjustments includes a positive adjustment for ASM participants with higher than median HCC scores and the cost EBCMs scored in the cost ASM performance category utilizes an advanced risk adjustment formula as discussed in section III.C.2.d.(3)(c) and III.C.2.d.(3)(d) of the final rule. Additionally, the EBCMs include comprehensive exclusion criteria for both the heart failure and low back pain episodes. We expect that the advanced therapies the commenter is referring to would most likely meet those EBCM exclusion criteria.

After consideration of public comments, we are finalizing our final score calculation proposal at § 512.745(a)(5) as proposed.

(6) ASM Performance Report

We proposed at § 512.745(b) to release an ASM participant's final score for each ASM performance year through an "ASM performance report," which we proposed to define at § 512.705 as the notification that CMS provides to the ASM participant for each ASM performance year, which contains the information specified at § 512.745(b). We proposed at § 512.745(b)(1) through (7) that the ASM performance report would, at minimum, provide each ASM participant: (1) individual measure-level scores for each of the measures required under each ASM performance category; (2) ASM performance category-level scores; (3) complex patient scoring adjustment, as applicable; (4) small practice or solo practitioner scoring adjustment, as applicable; (5) final score, and (6) the applicable ASM payment adjustment factor and (7) ASM payment multiplier for the applicable ASM payment year as discussed in section III.C.2.f of this final rule. As proposed, the ASM performance reports would not contain any protected health information or personally identifiable information of beneficiaries.

Accordingly, we would share the ASM performance reports with ASM participants as a matter of course without following the attestation and data sharing agreement process for CMS sharing of beneficiary-identifiable information proposed in section III.C.2.j. of this final rule.

We believe that the proposed approach to releasing ASM participant data would be a transparent way to help the ASM participant understand their performance on each of the required measures, activities, attestations, how those individual scores roll up to an overall ASM performance category score, and then how each ASM performance category score rolls up into the final score. We believe that this ASM performance report would be complementary to the other proposed data sharing approaches discussed in section III.C.2.j. of this final rule.

We solicited comments on our proposal at § 512.745(b) to provide ASM participants with an ASM performance report for each ASM performance year. We also solicited comments on the proposed components of the ASM performance report.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters offered recommendations on the proposed approach to provide ASM participants with an ASM performance report for each ASM performance year. The commenters suggested CMS to provide clinicians with more timely, interim performance feedback on patient quality, cost, and service utilization, noting that faster feedback would help clinicians monitor progress, adjust interventions, reduce care variation, and eliminate avoidable services, supporting continuous improvement. The commenters specifically recommended that CMS deliver timely and actionable feedback, including Medicare claims data, in real time or at regular monthly or quarterly intervals. A commenter recommended CMS to develop improvement activities that utilize real-time, actionable data, enabling physicians and care teams to promptly review and enhance patient care and office protocols. A few commenters recommended that CMS implement safeguards to account for data fluctuations and provide more frequent, real-time data sharing and reporting, noting that clinician and patient attribution data from ASM is currently unavailable until 2 years after the performance year. A commenter suggested CMS to develop and provide a standardized scoring calculator or dashboard tool to assist clinicians in real-time performance tracking and planning to promote transparency, reduce administrative burden, and

support compliance. A commenter expressed concerns with retroactive data, emphasizing that timely information is essential for clinical practice transformation. Another commenter also recommended that CMS provide retrospective cost data from up to 2 years prior to the measurement year, along with intermittent reporting during the ASM performance year, to improve visibility into cost trends.

Response: We appreciate the commenters for providing feedback on our proposal to provide ASM participants with an ASM performance report for each ASM performance year. We understand the commenters' desires for timelier, and interim performance feedback reports as well as calculators and dashboard tools to understand their performance. We are exploring ways to provide participants with the right data at the right intervals to assist them throughout the performance year. Though we did not consider the recommendations to provide retrospective cost, and real time improvement activity data to participants, if we did, we would do so in future notice-and-comment rulemaking.

Comment: A few commenters offered additional recommendations to CMS regarding the proposed ASM performance report. The commenters recommended that CMS provide performance data in a clear, publicly accessible format. Another commenter suggested CMS to offer training to assist smaller practices to interpret and act on information in the ASM performance report.

Response: We appreciate the commenters' suggestions on the ASM performance report. The proposed ASM performance report, as proposed, would help ASM participants understand their performance on each of the required measures, activities and attestations, as well as their resulting payment adjustment information. To assist providers, both large and small, who may struggle to follow the ASM performance report, we plan to offer educational resources and ad hoc support (for example, help desk support) on the data contained in the ASM performance report as those reports become available. We also acknowledge the commenters' suggestions on making performance data available in a clear and publicly accessible format. We will consider this suggestion and determine whether it would be appropriate and feasible to share this performance data in a public manner.

Comment: A commenter did not support the proposed approach to provide ASM participants with an ASM performance report for each ASM performance year, noting that delayed feedback mechanisms hinder meaningful improvement, while disproportionately burdening providers who care for high-risk populations with complex needs.

Response: We appreciate the commenters for providing feedback on our proposal to provide ASM participants with an ASM performance report for each ASM performance year. We understand the commenters' concerns and are exploring ways to provide participants with the right data at the right intervals to assist them throughout the performance year. We also intend to make efforts to provide performance data to ASM participants in a more timely manner following the data submission deadline.

After consideration of public comments, we are finalizing our definition of "ASM performance report" as proposed at § 512.705. We are also finalizing our proposal to provide ASM participants with an ASM performance report for each ASM performance year, including the proposed components of the ASM performance report, as proposed at § 512.745(b).

f. Payment Approach

(1) Payment Approach

In this section, we discuss our payment methodology to use an ASM participant's final score to determine net positive, neutral, or negative payment adjustments to an ASM participant's future Medicare Part B payments for an applicable ASM payment year.

ASM will test whether payment adjustments to ASM participants' future Part B FFS payments would preserve or improve the quality of care for beneficiaries with ASM's targeted chronic conditions receiving service from ASM participants while reducing program expenditures. Determining payment adjustments based on an ASM participant's performance across the ASM performance categories relative to other specialists furnishing services related to each of ASM's targeted chronic conditions directly incentivizes performance improvement through financial incentives. We believe the individualized payment adjustments under ASM would be reflective of the range of performance of specialists caring for beneficiaries with ASM targeted chronic conditions. As discussed in section III.C.1. of this final rule, we believe that the risk of a potential negative payment adjustment coupled with the incentive of a potential positive payment adjustment would incentivize the quality improvement and reduced low-value care spending that we aim to achieve through ASM. This type of risk arrangement would reward high performance and encourage ASM participants to improve the quality of care that they furnish to Medicare beneficiaries with ASM's targeted chronic conditions. Further, we believe that this type of incentive payment approach aligns with existing value-based purchasing programs, such as the Quality Payment

Program, in which ASM participants may have previously participated, and through which they may have received payment adjustment on future Medicare Part B payments based on their performance in MIPS.

We believe our payment methodology for an ASM participant to receive a positive, neutral, or negative payment adjustment based on their performance creates a strong incentive to promote performance improvement and achieve ASM's objectives.

(2) Payment Methodology Overview

In the CY 2026 PFS proposed rule, we proposed at § 512.750 a payment methodology for ASM where we would distribute, based on performance and in the form of scaled payment adjustments, a portion of the Medicare Part B payments paid to ASM participants for covered professional services during an ASM performance year, which would result in net positive, neutral, or negative payment adjustments during an ASM payment year. Accordingly, we proposed to define at § 512.705 an "ASM incentive pool" that would be a fixed percentage of the total amount of Medicare Part B covered professional service claims paid to ASM participants with final scores within an ASM cohort during an ASM performance year that would be distributed in in the form of scaled payment adjustments during an ASM payment year. We would calculate an ASM incentive pool for each ASM cohort for each ASM payment year as described at § 512.750(c)(1)(iii). The ASM incentive pool would be the total amount of funds that we would use to calculate scaled payment adjustments for an ASM payment year. We proposed to separately calculate an ASM incentive pool for each ASM cohort. For example, we would calculate a separate ASM incentive pool for the ASM heart failure cohort and ASM low back pain cohort. As discussed later in this section of this final rule, we would not prospectively withhold a portion of Part B payments for covered professional services during an ASM performance year to create the ASM incentive pools but would instead create virtual incentive pools based on actual spending during the ASM performance year.

In the CY 2026 PFS proposed rule, we also proposed to define at § 512.705 an "ASM payment adjustment factor" as a percent value based on an ASM's participant's final score as described at § 512.750(c)(1) that we use in calculating adjustments to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year. Based on their performance, an ASM participant could earn an ASM payment adjustment factor percentage that is less than, equal to, or

more than the percentage of their Medicare Part B payments used to calculate the ASM incentive pool, leading to a net negative, neutral, or positive net payment adjustment. Similar to our proposal to calculate separate ASM incentive pools for each ASM cohort, we would determine ASM payment adjustment factors separately for each ASM cohort as described later in this section of this proposed rule. We also proposed to define at § 512.705 an "ASM payment multiplier" as the numerical value equal to 1 plus the ASM payment adjustment factor determined for the ASM participant for an applicable ASM payment year as described at § 512.750(c).

As proposed at § 512.750(a) in the CY 2026 PFS proposed rule, to adjust payments, the amount otherwise paid under Medicare Part B for covered professional services furnished by an ASM participant during an ASM payment year would be multiplied by the ASM participant's ASM payment multiplier unless that ASM participant receives no payment adjustment (that is, a neutral payment adjustment) as described at § 512.750(d) because they do not receive a final score for the corresponding ASM performance year. We refer readers to § 512.745(a)(2) and section III.C.2.e.(2) of this final rule for policies related to final scores. We also refer readers to section III.C.2.f. of this final rule and § 512.750(f) for further policies on how payment adjustments will be applied in the case the ASM participant bills during an ASM payment year under a different TIN than the TIN we used to identify them as an ASM participant for the corresponding ASM performance year.

The proposed payment methodology is similar in design to existing incentive payment structures in CMS value-based programs, such as the Hospital Valued-Based Purchasing Program (Hospital VBP Program)[288] and the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP Program).[289]

● The Hospital VBP Program rewards acute care hospitals with incentive payments based on the quality of care they provide, rather than just the quantity of services they provide. The statutory requirements of the Hospital VBP Program are set forth in Section 1886(o) of the Social Security Act. The program uses selected measures that were first specified under the Hospital Inpatient Quality Reporting Program as established by section 1886(o)(2)(A) of the Act and defined at § 412.164(a).[290] A fixed percentage withhold of base operating Diagnosis-Related Group (DRG)

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[288] https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing.
[289] https://www.cms.gov/medicare/quality/nursing-home-improvement/value-based-purchasing.
[290] https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing.

payments for each discharge during an applicable fiscal year determines the amount of money that can be redistributed to participating hospitals through value-based incentive payments based on a participating hospital's total performance score. A hospital may earn back a value-based incentive payment percentage that is less than, equal to, or more than the applicable reduction for that program year (88 FR 59063 through 59108).

● Section 215 of the Protecting Access to Medicare Act of 2014 and subsequent additions of sections 1888(g) and (h) of the Act established the SNF VBP Program.[291] Then, section 111 of the Consolidated Appropriations Act, 2021 amended section 1888(h) of the Act to allow the Secretary to apply up to 9 additional measures to the SNF VBP Program.[292] The SNF VBP Program requires CMS to evaluate SNFs based on their performance on multiple measures, including improvement and achievement, provide quarterly performance reports to SNFs, and calculate incentive payments for SNFs based on their performance (88 FR 53276 through 53304).[293] To determine and fund the statutorily required incentive payments, CMS withholds 2 percent of SNFs' Medicare FFS Part A payments to fund the SNF VBP Program. CMS then redistributes 60 percent of this total withhold to SNFs as incentive payments, which CMS applies prospectively to all Medicare FFS Part A claims paid under the SNF Prospective Payment System (PPS) for the applicable program year (82 FR 36619 through 36621).

Our proposed payment methodology differs from the Hospital VBP Program and the SNF VBP Program in that we did not propose a prospective withhold of ASM participants' Medicare Part B payments during an ASM performance year. Instead, we proposed to determine a virtual ASM incentive pool as a fixed percentage of ASM participants' Medicare Part B covered professional service payments during the ASM performance year. We proposed that we would then distribute this virtual incentive pool through scaled payment adjustments on ASM participants' future Medicare Part B payments during an ASM payment year. The size of each ASM incentive pool and the distribution of final scores within each ASM cohort would together influence the possible magnitude of the scaled payment adjustments and the distribution of net negative, neutral, and positive payment adjustments. As discussed earlier and later in this section of the CY 2026 PFS proposed rule (90 FR 32605), we proposed to calculate ASM incentive

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[291] 42 U.S.C 1395yy(h).
[292] 42 U.S.C 1395yy(h).
[293] https://www.cms.gov/medicare/quality/nursing-home-improvement/value-based-purchasing.

pools, ASM payment adjustment factors, and ASM payment multipliers separately for each ASM cohort. The higher an ASM participant's final score, the greater the likelihood that they would receive a positive payment adjustment. Under this proposed methodology, the ASM participant's performance during an ASM performance year would not have an immediate financial impact but would result in a future net payment adjustment determined by the ASM participant's performance relative to other ASM participants. We stated that we believed that this proposed payment methodology would allow ASM to create net positive, neutral, and negative payment adjustments based on the annual distribution of final scores in each ASM cohort.

We also recognize that MIPS, under the Quality Payment Program, uses a value-based purchasing approach but determines payment adjustments based on performance relative to a performance threshold. In accordance with section 1848(q)(6) of the Act and § 414.1405(b), MIPS compares each MIPS eligible clinician's final score against the performance threshold established for that MIPS payment year and against the other MIPS eligible clinicians in a single comparison pool to determine whether each MIPS eligible clinician will receive a positive, negative, or neutral payment adjustment. As defined at § 414.1405, scores equal to the defined performance threshold receive a neutral (zero percent) payment adjustment. Scores falling below one-quarter of the performance threshold receive a negative adjustment of minus 9 percent, while scores between one-quarter of the performance threshold and the performance threshold receive a negative payment adjustment of less than zero percent and up to minus 9 percent based on a linear sliding scale. Scores above the performance threshold can receive positive payment adjustments greater than zero percent and up to positive 9 percent based on a linear sliding scale. Depending on the range of scores within a given MIPS performance period, a scaling factor (ranging from zero to 3) is applied to the positive adjustments to retain budget neutrality.

We considered, but decided not to propose, a payment methodology that includes a performance threshold like MIPS uses to determine ASM payment adjustment factors. To determine a MIPS payment adjustment factor for each MIPS eligible clinician for a MIPS performance period, CMS compares the MIPS eligible clinician's final score for the given year to the performance threshold CMS established for that same year in accordance with Section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that CMS compute the performance threshold such that it is the mean or median (as selected by

the Secretary) of the final scores for all MIPS eligible clinicians with respect to a "prior period" specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years. For each CY performance period/MIPS payment year, we have finalized a performance threshold based on the mean final score of all MIPS eligible clinicians from a previous MIPS performance period, as set forth in § 414.1405(b)(4) through (10). CMS establishes the performance threshold via rulemaking prior to the beginning of each MIPS performance period.

Adopting a similar performance threshold and payment adjustment approach for ASM would introduce several operational complexities. First, given the proposed separate comparison of final scores and separate calculation of ASM payment adjustment factors and ASM payment multipliers for each ASM cohort, we would need to determine a performance threshold for each ASM cohort for each ASM performance year. Because ASM is a new Innovation Center model, we would need to set a prospective performance threshold for the first ASM performance year without historical data on final scores. This lack of historical data could present challenges in calibrating the performance threshold to actual performance within the first ASM performance year. Second, we believe that a payment methodology that leverages a prospective performance threshold would limit the magnitude of ASM's negative and positive payment adjustments and, ultimately, the model's incentives to improve performance compared to our proposal to scale the payment adjustments distributed to ASM participants to equal the amount of an ASM incentive pool. For example, if a larger proportion of participants score above the performance threshold relative to the proportion of participants who score below the performance threshold, then the positive payment adjustments for those participants scoring above the performance threshold may be smaller in magnitude due to there being fewer negative adjustments from participants scoring below the performance threshold that can be distributed in positive payment adjustments.

We solicited comment on our overall payment approach for ASM, which would include an ASM incentive pool that is distributed in the form of scaled payment adjustments to ASM participants' future Medicare Part B payments based on their performance. We also sought comments on the alternative approach we considered that would use a performance threshold similar to MIPS in our payment methodology. We also sought comments on our proposed definitions of "ASM incentive pool," "ASM payment adjustment factor," and "ASM payment multiplier."

We received public comments on our overall proposed payment approach. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed two-sided financial risk in ASM, giving specialists more opportunities to move into accountable care arrangements. However, the commenters recommended a change in the payment incentives to move away from traditional FFS Medicare towards population-based payment and alignment. A commenter supported the proposed two-sided risk and suggested that assumption of risk is critical to minimize selection bias and development of generalizable results.

Response: We appreciate commenters for the support of the two-sided financial risk in ASM's payment approach. We also appreciate the commenter's support of two-sided risk under a mandatory model as it would provide more generalizable evaluation results. We agree that ASM would provide opportunities for select specialists to move into accountable care arrangements. ASM's payment approach allows for ASM participants to achieve payment adjustments on traditional FFS Part B payments while participating in other population-based payment models, such as shared savings initiatives. We believe that the flexible model overlap creates complementary incentives to improve quality and reduce unnecessary spending for beneficiaries with ASM's targeted chronic conditions.

Comment: A commenter supported calculating the proposed ASM payment adjustment by withholding Part B payments and suggested implementing a retrospective withhold of hospital-based Part A payments for distribution, to leverage savings from avoiding unnecessary procedures, which are a primary source of potential savings that are challenging to capture.

Response: We appreciate the commenter for their support of the overall ASM payment methodology. We note that the proposed payment methodology did not include a prospective withhold. Instead, we proposed that we would scale ASM payment adjustments factors so that the expected value of the negative adjustments would be larger than the expected value from the positive adjustments, resulting in a net savings to Medicare (90 FR 32606). While we expect that ASM would create downstream incentives to reduce hospital-based Part A payments for services related to ASM's targeted chronic conditions, this type of adjustment would be outside of the scope of ASM given its focus on FFS spending by specialists in the ambulatory spending.

Comment: A few commenters did not support the proposed ASM financial structure, which could lead to blanket reductions in payment to all ASM participants and relies on median scores, quality performance, and cost measure data that are typically not available to ASM participants until well beyond the ASM performance year. A commenter shared their belief that savings to the Medicare program should not be generated by reduced payments to physicians.

Response: We appreciate commenters raising their concerns about the proposed ASM financial structure. However, we note that ASM's payment approach would not lead to blanket payment reductions to all ASM participants. As we stated in the CY 2026 PFS proposed rule, there would not be a prospective withhold on ASM participants' Part B payments (90 FR 32606). While ASM payment adjustments factors would be calculated so that the expected value of the negative adjustments would be larger than the expected value of the positive adjustments, some ASM participants would still earn net positive payment adjustments. Regarding the availability of quality measure performance data, most quality measures are not based on administrative claims (see section III.C.2.d.(2) of this final rule), meaning that ASM participants would be able to track their own performance on the required measures throughout an ASM performance year. As we discussed in section III.C.2.j. of this final rule, we are considering ways by which to provide ASM participants with more updated information on claims-based quality measures and cost measures during an ASM performance year to aid performance monitoring in advance of data submission.

Comment: A few commenters suggested delaying the model and proposed ASM payment adjustments allowing CMS time to create a model that would not result in negative payment adjustments for ASM participants below the median final score, regardless of their improvements in care quality or cost efficiency. Further, the commenters shared their belief that delaying the model by a year or more would allow clinicians to gain experience with ASM measures, feedback information that can be used to improve patient care, and time to develop new staff resources and update workflows. A few commenters noted that ASM performance should be based on achievement and improvement.

Response: We appreciate commenters expressing their concerns on the planned start of ASM on January 1, 2027 and the possibility of negative payment adjustments in the first ASM payment year in CY 2029. We believe that our participant notification policies discussed in section III.C.2.c.(5) of this final

rule would provide adequate time for a selected ASM participant to become familiar with the required measures and make the necessary workflow adjustments to meet the model's requirements. As we discuss in our response to comments on the proposed exchange function in section III.C.2.f.(4).(c) of this final rule, use of an ASM cohort's median final score in the exchange function does not inherently mean that ASM participants scoring below that median would automatically receive a negative ASM payment adjustment factor. As discussed in the CY 2026 PFS proposed rule, use of the median final score within the proposed logistic exchange function would mean that more ASM participants would be likely to receive positive ASM payment adjustment factors compared to centering the function at 50 points, which represents the midpoint of the possible range of final scores (90 FR 32613). We appreciate the commenters' recommendations to incorporate improvement scoring into our scoring approaches. While we did not consider this into our scoring approaches in the CY 2026 PFS proposed rule, should we do so, we would do so in future notice-and-comment rulemaking.

Comment: A commenter recommended additional weighting of planned Shared Savings Program metrics of index patient admission and readmission rates rather than the weighting of the risk payments if the specialists are not ready for the downside risk in ASM.

Response: We appreciate the commenter for their recommendation. While some ASM participants may be associated with a Shared Savings Program ACO, we do not believe that it would be appropriate at this time to include Shared Savings Program metrics as part of the performance assessment for determining payment adjustments under ASM. As we discussed in section III.C.2.m. of this final rule, we designed ASM so that ASM's incentives could be layered with incentives introduced by other models or shared savings initiatives, such as the Shared Savings Program. As we are not differentiating between ASM participants that are and are not ready for downside risk under ASM, we do not believe that using planned Shared Savings Program metrics for a subset of ASM participants would be an appropriate performance measurement approach by which to determine payment adjustments.

Comment: Several commenters supported the alternative approach of establishing a performance threshold prior to the start of each ASM performance year that would clearly define the level of achievement needed to avoid negative payment adjustments and provide a benchmark and to minimize uncertainty for ASM participants. A few commenters recommended eliminating a tournament scoring

model in which the ASM participant's payment adjustment is dependent on whether their performance exceeds the majority of other ASM participants each year. A commenter recommended an implementation strategy that encourages gradual participation and performance improvement while ensuring fairness.

Response: We appreciate commenters for the feedback on an alternative approach to using a performance threshold, similar to what is used in MIPS, in ASM's payment methodology. While we acknowledge that the use of a prospectively determined final score performance threshold that determines whether an ASM participant would receive a positive or negative payment adjustment would provide ASM participants with a target for their final scores, we do not believe that it would be appropriate for ASM. As we discussed in the CY 2026 PFS proposed rule, we believe that our payment approach mirrors the general market for goods and services, which does not provide an upfront guarantee of a certain market share or profit margin based on a predetermined threshold of performance (90 FR 32607). The use of a performance threshold could lead to smaller net positive payment adjustments if an overly high proportion of ASM participants were to have final scores exceeding the performance threshold. As we received feedback during the development of the model that the magnitude of upside adjustments would need to be meaningful to engender the practice transformations that ASM aims to achieve, we believe that using an approach that creates a consistent incentive for all ASM participants to continually improve performance on the required measures and attestations is preferable. As discussed in section III.C.2.d. of this final rule, we intend to keep the requirements of each ASM performance category consistent across ASM's model test period. Following the first ASM performance year, ASM participants would have more detailed feedback on their performance relative to other ASM participants in their applicable ASM cohort, which would allow them to calibrate their performance improvement goals for future ASM performance years. As discussed in section III.C.2.j. of this final rule, we are considering ways to provide ASM participants with data on performance during an ASM performance year to allow ASM participants to calibrate their performance improvement goals.

Comment: A few commenters expressed concerns about the model's ability to accurately reflect clinician performance, measure improvement from previous performance periods and assess payment impacts. Specifically, a few commenters expressed concerns about recognizing high performance in ASM

and the fairness of assessing performance in the first ASM performance year, without a baseline for comparison.

Response: We appreciate the commenters but disagree with their concerns that ASM would not be able to measure clinician performance or assess payment impacts as a result of participation in ASM. As discussed in the CY 2026 PFS proposed rule, ASM's performance measurement framework leverages the tested MVP framework used in creating value-based incentives for eligible clinicians receiving Medicare FFS payments (90 FR 32573). While ASM will include substantive enhancements to this performance measurement framework to make more like-to-like comparison of clinicians who treat similar conditions, we believe that using quality, cost, and Promoting Interoperability measures that would be familiar to most ASM participants would allow us to appropriately evaluate clinician performance over time and to evaluate whether ASM achieves its overall objectives. We also appreciate the commenters' feedback on performance assessment within the first ASM performance year. The use of measures and attestations that would be familiar to many ASM participants, as well as our advanced notification of mandatory participation, leads us to believe that it would be fair to compare ASM participant performance for the first ASM performance year. As discussed in section III.C.2.j. of this final rule, we are considering ways to provide ASM participants with data that would potentially help them understand some aspects of their quality and cost performance during the first ASM performance year.

Comment: A few commenters recommended that payment could be provided upfront for ASM participants to assist practices in investing in updated processes, infrastructure and other practice improvements, noting concerns that the lag in reimbursement and mandated participation create financial strain and force clinicians into value-based models before they are truly ready or have the necessary capabilities. A few commenters suggested that this upfront financing or a monthly billing procedure to support enhanced preventive care, coordination with primary care physicians, care management, and other services that could improve outcomes for patients. These commenters suggested the ability to bill transitional care management (TCM), principal care management (PCM), and chronic care management (CCM) codes.

Response: We appreciate the commenters for their recommendations to have upfront infrastructure payments to support ASM participants' readiness. We did not propose these types of

payments in the CY 2026 PFS proposed rule nor did we solicit comment on them, and therefore, these comments are out of scope. As discussed in section III.C.2.d. of this final rule, we believe that the majority of ASM participants would be familiar with many of the ASM performance category requirements by virtue of previous participation in the Quality Payment Program and because the quality measures are directly related to the care provided by the included specialties. We also believe that the advanced notification of mandatory participation as described in section III.C.2.c.(5) of this final rule would provide ASM participants with time to prepare for the model requirements, such as adjusting workflows. We also would like to clarify that we are not excluding any specific PFS codes under ASM. As long as ASM participants meet the criteria and follow the rules for the TCM, PCM, or CCM codes, they can bill them.

Comment: Several commenters suggested that CMS consider alternative incentives for ASM participants to prevent reduction of payments for ASM participants regardless of their performance. A commenter recommended further efforts to move beyond FFS payments, and test payments such as a shared savings approach, bundled payments, lump sum rewards not tied to Part B payments or capitated payments. Another commenter suggested including approaches to assist clinicians in reducing avoidable Medicare spending on hospitalization and other services in lieu of payment reductions. A commenter recommended that CMS offer payment incentives to reward cost avoidance, such as reduction of emergency room visits, imaging and elective surgeries. Another commenter recommended that CMS explore alternative ASM incentives beyond FFS, such as lump sum rewards or capitated payments, to better reward providers for maintaining the health of their patients.

Response: We appreciate commenters for their suggestions on different alternative incentives that ASM could consider as part of its payment methodology. We did not propose or consider these incentives in the CY 2026 PFS proposed rule, so these comments are out of scope to the proposed provisions. Should we choose to consider them in ASM's payment methodology, we would do so through future notice-and-comment rulemaking.

Comment: A few commenters shared their concerns that carveouts are needed for fundamentally different and complex indications, noting that specialists' performance may be misrepresented due to statistical variability rather than actual care of quality or improvement. The commenters recommended

that CMS create safe harbors to prevent payment penalties when proprietary tools are unavailable on fair, non-discriminatory terms.

Response: We appreciate commenters for their suggestion related to the potential for unfair payment adjustments should performance be assessed on measures requiring proprietary tools. We refer readers to section III.C.2.d.(2) of this final rule for discussion related to the use of proprietary tools in required quality measures. We do not agree that payment carveouts or adjustments are needed by virtue of statistical variability in the required measures and attestations across the four ASM performance categories. We designed our performance assessment framework so that we would evaluate ASM participants on a focused set of utilization measures, evidence-based prevention and outcome measures, patient-reported outcome measures, and cost measures as applicable for each ASM targeted chronic condition. We believe that our scoring policies discussed throughout sections III.C.2.(d) and III.C.2.(e) of this final rule will appropriately evaluate ASM participant clinical performance so that we can make appropriate payment adjustments. We also note that we have broadly accounted for the medical and social complexity of beneficiaries to whom ASM participants furnish services by inclusion of the complex patient scoring adjustment in our final scoring methodology as discussed in section III.C.2.(e).(4) of this final rule. Should we consider a safe harbor to prevent payment penalties when proprietary tools are unavailable, we would do so through future notice-and-comment rulemaking.

Comment: A few commenters recommended that CMS tailor incentive payments for ASM participants to the unique needs of specialty surgery practices to account for their episodic, procedural, and resource-intensive nature.

Response: We appreciate the commenters' feedback that we should consider specific incentive payments for ASM participants in specialty surgical practices. As discussed earlier in this section of this proposed rule, we did not consider incentive payments as part of ASM's payment methodology and disagree that there are specific needs of specialty surgical practices that would require ASM-specific incentive payments. We believe that our participant eligibility criteria would identify appropriate surgical specialists who provide longitudinal care management for beneficiaries with low back pain by way of the EBCM attribution methodology. As ASM is not focused on surgical practices alone, we do not believe specific incentive payments for ASM participants in these practices are justified at this time.

Comment: A commenter expressed concern that the proposed ASM incentives may not sufficiently encourage meaningful collaboration of specialists with PCPs.

Response: We appreciate the commenters for their feedback related to how the incentives introduced through ASM's payment methodology may not encourage primary care collaboration. We note that the scoring of the improvement activities ASM performance category creates an incentive for ASM participants to collaborate with PCPs and that failure to meet this requirement could reduce an ASM participant's final score and increase the likelihood of a negative payment adjustment. We refer readers to section III.C.2.d.(4) of this final rule for further discussion on the required improvement activities. Should we consider additional financial incentives for primary care collaboration in the future, we would do so through notice-and-comment rulemaking.

Comment: A few commenters expressed concern that ASM relies heavily on MIPS infrastructure and transfers several existing challenges, including the MIPS scoring methodology that forces distribution of ASM performance scores and uses the maximum negative payment for the lower deciles. The commenters suggested CMS to create a floor for negative payment adjustments once ASM participants collectively improve outcomes.

Response: We appreciate the commenters for the feedback. While our ASM performance measurement framework leverages the MVP framework, ASM's scoring methodology discussed in section III.C.2.e. of this final rule makes several changes from that of MIPS, including different scoring policies within each ASM performance category, different adjustments to the final score, and a different weighting scheme for ASM performance categories in calculating the final score. We designed ASM's scoring methodology to more appropriately evaluate the performance of ASM participants and to determine payment adjustments. We note that our proposed payment methodology does not use the same determination of maximum negative payment adjustments for MIPS eligible clinicians that receive a score at or below one-fourth of the applicable performance threshold that is required under MIPS as described at § 414.1405(b)(2). As discussed later in this section of this final rule, ASM participants that receive a final score of zero would receive the maximum negative ASM payment adjustment factor for the applicable ASM payment year. We appreciate the recommendation on creating a floor of negative payment adjustments once ASM participants collectively improve outcomes but do not believe that this

would be appropriate for ASM as it could lead to a reduction in the magnitude of upside payment adjustments, which could lead to less meaningful incentives to improve quality and reduce unnecessary spending.

After consideration of public comments on ASM's payment approach, we are finalizing ASM's general payment methodology at § 512.750(a) as proposed. We did not receive any specific comments on our proposed definitions of ASM incentive pool, ASM payment adjustment factor, and ASM payment multiplier; therefore, we are finalizing their definitions as proposed at § 512.705.

(3) Comparison of ASM Participant Performance

We proposed at § 512.750(b) to separately compare the final scores of ASM participants in each ASM cohort to determine the payment adjustments for each ASM participant. We believe that the ASM participant eligibility criteria appropriately identify specialists that can be held accountable for cost, quality, and practice improvement for specific chronic conditions. Accordingly, we stated in the CY 2026 PFS proposed rule that we believed separately comparing ASM participants' final scores for each of the ASM targeted chronic conditions would provide more meaningful performance comparisons (90 FR 32607). Since each ASM cohort would be compared on the same set of requirements reported at the same TIN/NPI level (that is, the level at which an ASM participant is identified), the proposed performance comparison approach would allow for better differentiation in performance upon which to determine the payment adjustments.

Currently, under MIPS, performance measurement and the subsequent payment adjustment are based on a range of measures voluntarily reported by clinicians, each of whom receives a final score based on the submitted measures. A MIPS eligible clinician's performance is assessed against a pool of all clinicians, regardless of specialty type or the services they provide. In accordance with section 1848(q)(6) of the Act and § 414.1405(b), CMS compares each MIPS eligible clinician's final score against the performance threshold established for that MIPS payment year and against one another in a single comparison pool to determine whether each MIPS eligible clinician will receive a positive, negative, or neutral payment adjustment. CMS calculates MIPS payment adjustment factors in accordance with regulations at § 414.1405 (89 FR 61985). In ASM, we wish to test whether a more targeted approach where clinicians are evaluated: (1) on a set of relevant performance measures they are required to report;

and (2) among clinicians furnishing similar sets of services, would produce final scores and subsequent payment adjustments that are more reflective of clinician performance. We believe our proposed approach to separately compare ASM heart failure participants against other ASM heart failure participants and ASM low back pain participants against other ASM low back pain participants supports and incentivizes accountable care by creating more meaningful payment adjustments that differentiate and reflect ASM participant performance related to the chronic condition for which we believe the ASM participant should be accountable.

We considered not separating ASM participants in each ASM cohort when comparing final scores to determine ASM payment adjustment factors and ASM payment multipliers, and instead, comparing the final scores of all ASM participants together. This approach would potentially be administratively easier to operationalize and would align with the current practice of comparison under MIPS as defined at § 414.1405. It would also potentially lead to a more varied distribution of final scores that would translate into a more varied distribution of payment adjustment, which could be helpful in creating the desired payment incentives. However, we believe that comparing performance within each ASM cohort is more appropriate in meeting our aim to test whether like-to-like performance comparisons based on a clinically relevant measure set and the resulting payment incentives achieve ASM's objectives of increasing accountability for specialty care related to ASM targeted chronic conditions.

We also believe that comparing performance using a continuous distribution of final scores would result in more meaningful incentives for ASM participants because payment adjustments would be determined on relative performance across ASM participants instead of relative to a prospectively determined performance threshold. This approach also more closely mirrors the general market for goods and services, which does not provide an upfront guarantee of a certain market share or profit margin based on a predetermined threshold of performance. Rather, ASM participants would compete to provide the highest quality, most efficient care to ASM beneficiaries, and the top performers would receive positive payment adjustments—in the same way that competitive markets reward top performers with profits.

We solicited comments on our proposal at § 512.750(b) to determine ASM payment adjustment factors and ASM payment multipliers by comparing final scores separately among each ASM cohort. We

also sought comment on the alternative we considered comparing final scores of all ASM participants together, like the MIPS approach for comparing performance scores.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed incentive pools that are distinct and separate for each ASM cohort, allowing comparisons between peers, which is a significant step toward more meaningful measurement.

Response: We appreciate the commenters for their support of the proposal. We agree that comparisons within ASM cohorts would provide more meaningful performance assessment.

Comment: Several commenters supported the proposed comparison of clinicians within each ASM cohort but also expressed concerns regarding the fairness and appropriateness of comparisons. The commenters specifically noted factors such as variation in patient demographics, resource access and care infrastructure, which may require geographic or other adjustments in the ASM cohort methodology. The commenters suggested CMS to monitor the results of each ASM cohort in the model to ensure the complex patient adjustment and small practice scoring adjustments are properly sized. A commenter recommended that CMS examine approaches to ensure that ASM participants primarily supporting high-risk patients are not unfairly penalized.

Response: We appreciate commenters' support for comparing clinicians within each ASM cohort and agree that this is the preferred way to compare performance in ASM. We understand that the context in which ASM participants furnish services may differ based on geographic or practice-level factors. As we discuss in section III.C.2.e. of this final rule, we believe that the complex patient and small practice scoring adjustments provide adequate and straightforward adjustments to support ASM participants that serve more medically or socially complex beneficiaries, or practice within a smaller setting to achieve a higher final score. As part of ASM's implementation, we would continue to monitor the complex patient and small practice scoring adjustments to determine if adjustments would be required to ensure those adjustments achieve their intended purpose and not unfairly penalize certain ASM participants. Any adjustments to those scoring adjustments would be done through future notice-and-comment rulemaking. We also refer readers to section III.C.2.d.(1).(b) of this final rule for further discussion on our provision to

allow ASM participants in small practices to report quality measures in the ASM quality performance category at the TIN level. We do not believe that allow this subset of ASM participants to report data at the TIN level would not undermine our performance comparison approach.

Comment: A commenter expressed a belief that the current ASM cohort definition may undermine the fairness of performance comparison fairness under ASM and presents a challenge in accurately attributing relevant measures and performance to any one clinician in the cohort.

Response: We appreciate the commenter for their feedback. We clarify that an ASM cohort includes individual ASM participants identified for a specific chronic condition. That is, the heart failure ASM cohort includes only ASM heart failure participants and the low back pain ASM cohort includes only ASM low back pain participants. Based on ASM's data submission requirements discussed in section III.C.2.d.(1) of this final rule, we believe that this data reporting and scoring structure does not create an issue with attributing relevant measures and performance to ASM participants in the cohort. Accordingly, we do not believe that this structure of the ASM cohort would lead to unfair performance comparisons.

Comment: Several commenters did not support the proposed comparison within an ASM cohort using a tournament style payment structure that potentially penalizes clinicians even if they significantly improve quality and reduce spending, discourage collaboration and the care of patients in the ASM cohort, and primarily focuses on cutting costs. The commenters recommended CMS to modify the methodology to reward any ASM participant that exceeds a predetermined performance threshold to incentivize care improvement.

Response: We appreciate the commenters for feedback on the proposed comparison approach and our proposal to not use a predetermined performance threshold of final scores within our payment methodology. As we discuss in our response to comments earlier in this section of this final rule, we believe that not using a performance threshold mirrors the general market for goods and services, which does not provide an upfront guarantee of a certain market share or profit margin based on a predetermined threshold of performance. The use of a performance threshold could also lead to smaller net positive payment adjustments if an overly high proportion of ASM participants were to have final scores exceeding the performance threshold. As we received feedback during the development of the model that

the magnitude of upside adjustments would need to be meaningful to engender the practice transformations that ASM aims to achieve, we believe that using an approach that creates a consistent incentive for all ASM participants to continually improve performance on the required measures and attestations is appropriate.

After consideration of public comments, we are finalizing our proposed approach to compare the final scores of ASM participants within each ASM cohort to determine ASM payment adjustment factors and ASM payment multipliers as proposed at § 512.750(b).

(4) Calculation of ASM Payment Adjustment Factors and ASM Payment Multipliers

In the CY 2026 PFS proposed rule, we provided an overview of the proposed process to calculate ASM payment adjustment factors and ASM payment multipliers (90 FR 32607). We also discussed the calculation of the ASM incentive pool using the "ASM risk level," which we proposed to define at § 512.705 as the magnitude of the maximum positive or negative net payment adjustment percentage to which an ASM participant would be subject during an ASM payment year as described at § 512.750(c)(1)(i), and the "ASM redistribution percentage," which we proposed to define at § 512.705 as a percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that CMS distributes in the form of payment adjustments to ASM participants during an ASM payment year as described at § 512.750(c)(1)(iii).

We also discussed how we would convert final scores into ASM payment adjustment factors and ASM payment multipliers based on the ASM incentive pool and our proposed "exchange function," which we proposed to define at § 512.705 as the function used to translate an ASM participant's final score into an ASM payment adjustment factor as described at proposed § 512.750(c)(1)(ii). We also proposed to define at § 512.705 a "scaling factor" as a numerical value calculated by CMS to ensure that the total estimated payment adjustments in an ASM payment year are equal to an ASM incentive pool for an applicable ASM payment year as described at § 512.750(c)(1)(iv).

Finally, we discussed how these ASM payment multipliers would be applied to future Medicare Part B claims for covered professional services during an ASM payment year.

(a) Overview of ASM Payment Adjustment Factors and Payment Multiplier Calculation Process

We proposed at § 512.750(c) to use the following process to calculate ASM payment adjustment factors and ASM payment multipliers for each ASM payment year for ASM participants with final scores for the corresponding ASM performance year. We refer readers to Table B-D8 in section III.C.2.e.(2) of this final rule for a summary of how an ASM participant's final score influences their payment adjustment.

Calculation of ASM Incentive Pool

● Step 1. Calculate total Medicare Part B payments for covered professional services made to ASM participants with final scores in each ASM cohort during an ASM performance year.

● Step 2. Multiply the total calculated in Step 1 by the ASM risk level for each ASM payment year proposed at § 512.750(c)(1)(i) and discussed in section III.C.2.f.(4).(b).(i) of this final rule.

● Step 3. Multiply the amount calculated in Step 2 by the ASM redistribution percentage proposed at § 512.750(c)(1)(iii) and discussed in section III.C.2.f.(4).(b).(ii) of this final rule to determine the total ASM incentive pool amount available for payment adjustment for each ASM cohort.

Calculation of ASM Payment Adjustment Factor

● Step 4. Convert each ASM participant's final score into a transformed numerical final score by using the exchange function proposed at § 512.750(c)(1)(ii) and described in section III.C.2.f.(4).(c) of this final rule.

● Step 5. Calculate a scaling factor as proposed at § 512.750(c)(1)(iv) to ensure that the sum of applied ASM payment adjustment factors would equal the ASM incentive pool for each ASM cohort. The scaling factor is calculated by dividing the total amount in the ASM incentive pool (calculated in Step 3) by the sum of all ASM participant's transformed final scores (calculated in Step 4) multiplied by their respective total Medicare Part B covered professional services payments and the ASM risk level.

● Step 6A. For ASM participants that receive a final score greater than zero as described at § 512.745(a)(2)(i), calculate an ASM payment adjustment factor for each ASM participant within each ASM cohort by multiplying the ASM risk level, the ASM participant's transformed final score (calculated in Step 4), and the scaling factor (calculated in Step 5), and then subtracting the ASM risk level from this product as described at § 512.750(c)(1)(i):

$$\text{ASM payment adjustment factor} = (\text{ASM risk level} \times \text{transformed final score} \times \text{scaling factor}) - \text{ASM risk level}$$

● Step 6B. For ASM participants that receive a final score of zero as described at § 512.745(a)(2)(ii), calculate the ASM payment adjustment factor for each ASM participant equal to the negative of the applicable ASM risk level as described at § 512.750(c)(1)(i).

Calculation of ASM Payment Multiplier

● Step 7. Calculate the ASM payment multiplier for each ASM participant by using the following formula as described § 512.750(c):

$$\text{ASM payment multiplier} = 1 + \text{ASM payment adjustment factor}$$

Under this proposed calculation process, an ASM payment adjustment factor could be negative (meaning net negative payment adjustments), zero (meaning neutral or no payment adjustments), or positive (meaning net positive payment adjustments). Accordingly, an ASM payment multiplier above 1 would result in net positive payment adjustments; an ASM payment multiplier of 1 would result in no (that is, neutral) payment adjustments, and an ASM payment multiplier less than 1 would result in a net negative payment adjustment.

We proposed at § 512.750(d) that ASM participants who do not receive a final score as discussed in section III.C.2.e.(2).(b) of this final rule would receive an ASM payment adjustment factor of zero and an ASM payment multiplier of 1 (that is, a neutral payment adjustment) for the applicable ASM payment year.

To illustrate how this process would work, we provided the following example of how we would calculate the ASM payment adjustment factor and ASM payment multiplier for individual ASM participants who received a final score greater than zero. In this example, we assumed an ASM risk level of 9 percent and an ASM redistribution percentage of 85 percent.

● Step 1. We determine that all ASM participants with final scores in the example ASM cohort had a total of $1 billion in Medicare Part B covered professional service payments during the ASM performance year.

● Steps 2 and 3. We multiply the $1 billion calculated in Step 1 by the 9 percent ASM risk level and the 85 percent ASM redistribution percentage to determine an ASM incentive pool of $76.5 million for this example.

● Step 4. An ASM participant, in this example, received a final score of 80 points and the median score for the example ASM cohort was 50 points. When transformed under the exchange function, this final score would result in a transformed final score of 0.95.

● Step 5. We calculate a scaling factor of 1.5 applicable for all ASM participants in this example ASM cohort to ensure that the amount in the ASM incentive pool would be distributed in the form of scaled payment adjustments. The numerator of the scaling factor would be the $76.5 million in the ASM incentive pool (calculated in Steps 2 and 3) and the denominator would be calculated as $51 million based on the sum of all ASM participant's transformed final scores multiplied by their respective total Medicare Part B covered professional services payments and the 9 percent ASM risk level: ($76.5 million / $51 million = 1.5).

● Step 6A. The ASM payment adjustment factor, in this example, would be calculated as: [ASM risk level (9 percent) × transformed final score (0.95) × scaling factor (1.5)] – ASM risk level (9 percent) = 0.0385

● Step 7. The resulting ASM payment multiplier, in this example, would be calculated as: 1 + ASM payment adjustment factor (0.0385) = 1.0385. The value of this ASM payment multiplier would mean that the example ASM participant would receive a positive adjustment of 3.85 percent on all Medicare Part B covered professional service payments during the corresponding ASM payment year. We note that the parameters of the previous calculation are fictitious and may look entirely different when calculating the ASM payment adjustment factors and ASM payment multipliers for the model, depending on the distribution of final scores, the magnitude of Medicare Part B covered professional service payments associated with ASM participants, the size of ASM incentive pool, among other factors.

As discussed earlier in this section of this final rule, we did not propose to use a performance threshold to determine a cutoff between positive and negative ASM payment adjustment factors and resulting ASM payment multipliers. We would, therefore, calculate ASM payment adjustment factors and resulting ASM payment multipliers based on the size of the ASM incentive pool and the distribution of

final scores for a given ASM performance year using the proposed payment methodology described throughout this section of this final rule.

The process to calculate ASM payment adjustment factors and adjust an ASM participant's Medicare Part B payments using an ASM payment multiplier during an applicable ASM payment year as proposed at § 512.750 aligned with the processes and timelines by which the Quality Payment Program applies MIPS payment adjustments for each Medicare Part B claim made for covered professional services furnished by a MIPS eligible clinician as defined at § 414.1405(e). We believed that aligning the timeline and processes with the Quality Payment Program's application of MIPS payment adjustments would ensure operational consistency and minimize confusion. As discussed in section III.C.2.e.(6) of the CY 2026 PFS proposed rule (90 FR 32605), we proposed to provide an ASM participant with their ASM payment adjustment factor and ASM payment multiplier in the ASM performance report provided to each ASM participant for the applicable ASM performance year.

We solicited comments on our proposed process as described at § 512.750(c) to calculate the ASM payment adjustment factors and ASM payment multipliers, and how we would apply ASM payment multipliers to an ASM participant's Medicare Part B payment during an ASM payment year.

We received public comments about our general proposal to calculate and apply ASM payment adjustment factors and multipliers. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposed calculation of the ASM payment adjustment, noting a high risk of negative financial impacts to ASM participants, uncertainty, lack of predictability, and payment delays. The commenters suggested CMS to reconsider the methodology by establishing clear performance standards and revising the financial structure to eliminate payment reductions. The commenters believed that these changes would potentially avoid unintended consequences, such as clinician burnout, shifts of employment type, adverse patient selection, reduced specialist collaboration, disproportionate burden on providers who care for high-risk populations, and limited incentives to improve care delivery.

Response: We appreciate the commenters for their suggestion on the proposed calculation of payment adjustments under ASM. We disagree with their suggestion to eliminate payment reductions as

we believe that two-sided risk is most appropriate for creating the right financial incentives to achieve ASM's objectives. While we recognize the challenges some clinicians face, as cited by the commenters, we believe that introducing a model that would incentivize improved upstream chronic condition management through two-sided risk is appropriate given the high prevalence and high spending related to ASM's targeted chronic conditions. We also note that we designed our final scoring policies, discussed in section III.C.2.e. of this final rule, so that ASM we would reward participants that provide care to higher-risk beneficiaries to avoid adverse beneficiary selection. With the complex patient scoring adjustment, ASM participants that care for a higher proportion of higher-risk beneficiaries would be more likely to receive a higher final score. We also disagree that ASM would create limited incentives to improve care delivery as we believe that the collective performance measurement approach and the payment methodology would hold specialists accountable for improving quality over time while finding ways to reduce the use of some unnecessary or low-value services.

After consideration of public comments, we are finalizing the proposed approach to calculate ASM payment multipliers, and ASM payment adjustment factors as proposed at § 512.750(c). We did not receive specific comments on our proposed calculation of the scaling factor, so we are finalizing that calculation as proposed at § 512.750(c)(1)(iv). Finally, we did not receive specific comments on our proposed definitions for ASM risk level, ASM redistribution percentage, exchange function or scaling factor. Therefore, we are finalizing their definitions as proposed at § 512.705.

We refer readers to the remainder of this section of this final rule for comments and responses related to additional components of ASM's payment methodology.

(b) ASM Incentive Pool

As discussed in the CY 2026 PFS proposed rule (90 FR 32608), we proposed to calculate the ASM incentive pool for each ASM cohort based on two factors: (1) the ASM risk level as described at § 512.705(c)(1) (that is, the magnitude of the maximum positive or negative net payment adjustment percentage to which an ASM participant would be subject during an ASM payment year) and (2) the ASM redistribution percentage as described at § 512.750(c)(1)(iii) (that is, the percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that would be distributed in the form of payment adjustments to ASM participants during an ASM payment

year). The total amount in an ASM incentive pool would directly determine the magnitude of ASM payment adjustment factors and resulting ASM payment multipliers that each ASM participant would receive during an ASM payment year. We discuss our proposals and public comments received on for the magnitude of ASM risk level and ASM redistribution percentage later in this section of this final rule.

We describe the step-by-step process of calculating the ASM incentive pool earlier in this section of this final rule. In summary, we proposed at § 512.750(c)(1)(iii) to calculate an ASM incentive pool for each ASM cohort for applicable for each ASM payment year using the following formula:

$$\begin{aligned}\text{ASM Incentive Pool} \\ &= \text{ASM risk level} \times \text{ASM redistribution percentage} \\ &\times \sum \text{ASM participant Medicare Part B payments}\end{aligned}$$

The proposed approach to calculating an ASM incentive pool aligns with the current approach that other CMS VBP programs use when calculating the total amount that can be distributed to program participants through payment adjustments. Both the SNF VBP Program (82 FR 36619 through 36621) and the Hospital VBP Program (88 FR 59063 through 59108) employ a similar calculation to determine the total amount that can be redistributed through payment adjustments for their respective program participants. We believe the proposed approach would determine an ASM incentive pool amount that would be appropriate to distribute through scaled payment adjustments, and that the proposed approach would align with the desired level of two-sided risk that we believe would incentivize behavioral change and increased accountability.

We solicited comments on our proposed approach to calculate the ASM incentive pool for each ASM cohort.

We received public comments on the calculation of the ASM incentive pool. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported pooling results from both ASM cohorts together in the proposed calculation formula for calculating the ASM incentive pool to prevent statistical variation due to low volumes and incentivize clinicians to work collaboratively.

Response: We appreciate the commenters for their suggestion to combine the ASM incentive pools for all ASM cohorts for the purpose of calculating ASM payment adjustment factors and

multipliers. Based on our performance comparison approach of comparing the final scores of each ASM cohort separately to ensure fair comparisons, we do not believe it would be appropriate to combine each cohort's ASM incentive pool. We do not believe that there would be statistical variation due to low volumes given the individual scoring policies of each ASM performance category discussed in section III.C.2.d. of this final rule. Further, we do not agree that pooling ASM incentives for two clinically different groups of specialists would create an incentive for collaboration nor does ASM require collaboration across ASM participants in different ASM cohorts given the different clinical nature of managing ASM's targeted chronic conditions.

After consideration of public comments, we are finalizing our proposed calculation of ASM incentive pools as proposed at § 512.750(c)(1)(iii). We did not receive any comments on our proposal that ASM participants who do not receive a final score would receive an ASM payment adjustment factor of zero and an ASM payment multiplier of 1 (that is, no payment adjustment); therefore, we are finalizing this proposed policy as proposed at § 512.750(d). We refer readers to comments and our responses, as well as our final provision, on the ASM redistribution percentage proposed at § 512.750(c)(1)(iii) in section III.C.2.f.(4).(b).(ii) of this final rule

(i) ASM Risk Level

As discussed, in the CY 2026 PFS proposed rule (90 FR 32609), we proposed to use the annual ASM risk level to calculate the ASM incentive pool for each ASM cohort. We proposed at § 512.750(c)(1)(i) establishing the ASM risk level that is the magnitude of the maximum downside or upside risk to which an ASM participant would be subject to during an ASM payment year. We proposed at § 512.750(c)(1)(i)(A) through (E) the risk levels for each ASM payment year as summarized in Table B-D9.

TABLE B-D9: ASM RISK LEVELS

ASM Performance Year	ASM Payment Year	ASM Risk Level
2027	2029	9 percent
2028	2030	9 percent
2029	2031	10 percent
2030	2032	11 percent
2031	2033	12 percent

Our proposed ASM risk level of 9 percent for the 2029 ASM payment year (based on 2027 ASM performance year performance) and the 2030 ASM payment year (based on 2028 ASM performance year performance) aligned with the CY 2024 applicable percent of 9 percent under MIPS, which is the maximum and minimum range of potential MIPS payment adjustment factor for a given MIPS payment year defined at § 414.1405(c) (88 FR 79378). Depending on the range of MIPS eligible clinicians' scores within a given MIPS performance period, a scaling factor (ranging from zero to 3) is applied to positive adjustments to retain budget neutrality as defined at § 414.1405(b)(3) (88 FR 79378), meaning that the maximum positive payment adjustment factor may be below or above the applicable percent. A MIPS eligible clinician with a score of zero receives a payment adjustment factor equal to the negative of the applicable percent as defined at defined at § 414.1405, meaning that all MIPS eligible clinicians are potentially subject to a maximum downside risk equivalent to the applicable percent. Based on our ASM performance category and scoring approach that leverages the MVP measurement framework (see section III.C.2.d of this final rule), we believe that starting and keeping the ASM risk level at 9 percent for the first two ASM payment years would be appropriate given its continued use within MIPS. We believe that gradually increasing the ASM risk level over time would provide an incentive for increased accountability that would be central to increasing accountability for longitudinal care management and improving the quality of care for beneficiaries with heart failure and low back pain.

We considered annual ASM risk levels higher and lower than what we proposed for each ASM performance year. Higher ASM risk levels would mean that ASM participants with lower final scores would be subject to potentially higher negative payment adjustments, whereas lower ASM risk levels would mean that ASM participants with lower final scores would be subject to potentially lower negative payment adjustments. Calibrating the right level of risk is critical to ensure that ASM participants will receive meaningful incentives to improve performance. We believe that starting with a level of downside risk already familiar to many ASM participants who previously participated in MIPS would be appropriate given that the application of ASM payment adjustment factors would be applied to Medicare Part B claims for covered professional services (as discussed earlier in this section of this final rule) in a similar fashion as MIPS as defined at § 414.1405(e).

While we proposed at § 512.745(a)(4) a small practice scoring adjustment in an ASM participant's final score, we also considered whether to reduce the ASM risk level for ASM participants in small practices. Given the systematic differences in historical MIPS performance of likely ASM participants in small practices that we observed and discuss in section III.C.2.e.(4) of this final rule, reducing the ASM risk level for ASM participants in small practices would be one way to prevent them from being unfairly penalized in their payment adjustments. We were, however, concerned that decreasing the ASM risk level for ASM participants in small practices to be lower than the equivalent applicable percent in MIPS as defined at § 414.1405(c) would be a disincentive for ASM participants in small practices to submit the required data under ASM and would potentially limit the magnitude of any net positive payment adjustments. We, therefore, believe that the proposed small practice scoring adjustment is a simpler and more transparent adjustment for ASM participants in small practices.

We also considered a similar adjustment in ASM risk level for ASM participants in a rural location as an alternative to the rural practice scoring adjustment that we considered in section III.C.2.e.(4) of this final rule. For the same reasons discussed in section III.C.2.e.(4) of this final rule, we decided not to propose a scoring adjustment for ASM participants in rural areas.

We sought comments on our proposed ASM risk level for each ASM payment year as part of our payment approach. We also sought comment on the alternative risk levels we considered for each ASM payment year. Finally, we sought comment on the alternatives we considered related to a lower ASM risk level for ASM participants in small practices and in rural areas.

We received public comments on the proposed ASM risk level. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for an alternative approach that would implement a glidepath, allowing ASM participants to have little to no risk in the first ASM performance year(s) or allow ASM participants to select their level of risk in the early ASM performance years of the model, as this approach would allow ASM participants time to understand their own comparison to peers in the ASM cohorts, build infrastructure, and make improvements, while also reducing financial burden, especially for small practices. A few commenters recommended that CMS mitigate financial risk and implement a "hold harmless" approach with no payment incentives for ASM participants during the first

ASM performance year, allowing clinicians a pilot year to validate attribution and scoring methods prior to receiving ASM payment adjustments.

Response: We appreciate commenters for the suggestion on the alternative ASM risk levels that we considered, including suggestions on a glidepath to more substantial levels of risk while ASM participants are becoming accustomed to the model's requirements. We believe that we plan to provide ample notification to selected ASM participants ahead of the model start date so that they can learn more about the model requirements and make the necessary adjustments within their practices to meet these requirements. We refer readers to section III.C.2.c.(5) of this final rule for further discussion on the finalized participation selection notification-related policies. We also intend to release resources for ASM participants on model requirements ahead of the model start. We do not believe that a "hold harmless" approach for the first ASM performance year and corresponding ASM payment year would achieve ASM's objectives as it would undermine the savings that we aim to achieve under ASM. Further, as many ASM participants would be accustomed to the 9 percent risk level under MIPS, we believe that starting the ASM risk level at 9 percent and maintaining it at 9 percent for the second ASM payment year is not introducing an undue level of risk. We believe that the gradual increase of the ASM risk level beginning in the third ASM payment year would incentivize continued performance improvement over the model test period. Regarding the suggestion for reducing the ASM risk level for small practices, we believe that the small practice scoring adjustment, as discussed in section III.C.2.e.(4) of this final rule, will support ASM participants in small practices to have a higher final score and increase the likelihood of receiving a positive ASM payment adjustment factor.

Comment: A commenter recommended that CMS implement a 1 to 2-year upside-only participation option in ASM for small and independent practices, noting that this would allow them to build infrastructure and reporting capacity before being held financially liable for potential negative ASM payment adjustments.

Response: We appreciate the recommendation on implementing a 1 to 2-year upside-only option for clinicians in small and independent practices. While we acknowledge that clinicians in small and solo practices face unique challenges in building the infrastructure and capacity to meet reporting requirements, we believe that the adequate notice of mandatory participation would allow ASM

participants time to prepare. Further, as many of the measures and requirements are similar to MIPS, we believe that many ASM participants in these types of practices would have capacities to meet ASM's requirements. Finally, the small practice and solo practitioner scoring adjustments would provide another safeguard to increase the likelihood of ASM participants in small or solo practices of achieving a positive payment adjustment.

Comment: A few commenters expressed concerns about the proposed risk levels in the model, which have not been previously tested, noting that payment reduction trajectories are unsustainable and could accelerate practice closures, worsen rural specialist shortages, harm small and integrative practices critical for prevention and functional improvement, destabilize clinicians with limited resources, encourage gaming, and ultimately reduce patient access.

Response: We appreciate commenters for their feedback on the proposed ASM risk levels and their concerns related to the potential impact of these adjustments. As designed, we do not believe that the downside risk level is unsustainable; we proposed to use the same risk level from MIPS for the first two ASM performance years and proposed to gradually increase that risk level by 1 percentage point each year beginning in the third ASM performance year. We believe this gives ASM participants adequate time to get accustomed to the model by the time the two-sided risk levels begin to increase while not exposing ASM participants to levels of risk that they would likely otherwise be subject to under MIPS. As we discussed in section III.C.2.e of this final rule, we have designed the complex patient and small practice scoring adjustments so that we would help offset the challenges commonly faced by these practice types. We believe that this would safeguard against undeserved penalties and from the potential other unintended consequences cited by the commenters. Finally, as part of ASM's evaluation and monitoring efforts, we would monitor for potential unintended consequences of ASM's payment approach. Any resulting adjustments to the payment approach as a result of these monitoring efforts would be done through future notice-and-comment rulemaking.

Comment: Many commenters expressed concern about the current proposed ASM risk level(s) and recommended the reduction of risk levels, for example, aligning with the 2 percent maximum penalty for hospitals in Hospital Value Based Purchasing Program or the 9 percent maximum penalty for MIPS. A commenter shared their belief that the proposal exceeds the budget neutral requirements set forth by the

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Another commenter recommended a stable downside risk of nine percent throughout the ASM model test period. The commenters also noted concern about burden and financial stability, especially for small and resource-constrained practices, resulting from an excessively ASM high risk level at a time when increases to clinician reimbursement already lag behind inflation.

Response: We appreciate commenters for sharing their concerns on the proposed magnitude of possible negative payment adjustments under ASM. We disagree with the suggestion of aligning with the 2 percent maximum penalty for hospitals in the Hospital Value Based Purchasing Program as the basis for that maximum penalty is based on Part A FFS spending, whereas ASM's payment methodology adjusts Part B FFS spending. As described in the CY 2026 PFS proposed rule (90 FR 32609), we believe that first aligning with the MIPS 9 percent maximum penalty would be appropriate because MIPS payment adjustments are on Part B FFS payments and many ASM participants would already be familiar with this level of risk if they participate in MIPS. We appreciate the commenters for their suggestion of maintaining an ASM risk level of 9 percent throughout the entirety of ASM's test period. While we agree that using the same ASM risk level for all ASM payment years would create consistency, we believe that gradually increasing the ASM risk level beginning in the third ASM payment year would provide a gradual but increasing risk level to incentivize improved performance over time. We appreciate commenters for raising their specific concerns related to financial instability that a high ASM risk level could introduce to ASM participants in small or resource-constrained practices. As we discuss in sections III.C.2.e.(3) and III.C.2.e.(4) of this final rule, we believe that the complex patient and small practice scoring adjustments will ensure that ASM participants in these contexts will be less likely to be unfairly penalized. We will also continue to monitor the impacts of these scoring adjustments on the payment adjustments for eligible ASM participants throughout the model test period. Finally, as an Innovation Center model under section 1115A(b) of the Act, ASM is not subject to the same budget neutrality requirements set forth in MACRA.

Comment: A commenter recommended specialty-specific risk adjustments for ASM participants.

Response: We appreciate the commenters for their feedback. We do not agree that specialty-specific risk adjustment within ASM's payment approach would be appropriate as it would undermine

ASM's approach to conduct more like-to-like comparisons of specialist performance. First, we believe that our ASM participant eligibility criteria identify specialists who we can appropriately evaluate performance related to ASM's targeted chronic conditions. Second, we note that select quality measures and the EBCMs are risk-adjusted for several factors directly related to the target conditions. Collectively, we believe that these measure-level risk adjustments, the complex patient and small practice scoring adjustments, as well as our ASM participant eligibility criteria would ensure that we are making appropriate like-to-like comparisons while accounting for practice-level factors that may lead to systematic differences in ASM participant performance.

After consideration of public comments, we are finalizing the proposed ASM risk levels as proposed at § 512.750(c)(1)(i)(A) through (E).

(ii) ASM Redistribution Percentage

As discussed in the CY 2026 PFS proposed rule (90 FR 32610), we proposed to set an ASM redistribution percentage that is the percentage of the Medicare Part B covered professional service payments to ASM participants during an ASM performance year multiplied by the applicable ASM risk level that would be distributed in the form of scaled payment adjustments to ASM participants during an ASM payment year. As discussed earlier in this final rule, we proposed to define the total amount available for distribution as the ASM incentive pool. We proposed at § 512.750(c)(1)(iii) an ASM redistribution percentage of 85 percent beginning with the 2029 ASM payment year. Under this proposed ASM redistribution percentage, 85 percent of Medicare Part B covered professional service payments to ASM participants during an ASM performance year multiplied by the applicable ASM risk level (that is, the value of the ASM incentive pool) would be distributed to ASM participants in the form of scaled payment adjustments. The other 15 percent of the Medicare Part B payments multiplied by the ASM risk level would be retained in the Medicare Trust Fund. To illustrate the scale of the net payment adjustments under these proposed policies, the proposed ASM redistribution percentage of 85 percent and an ASM risk level of 9 percent would lead to an estimated net 7.65 percent (that is, 85 percent multiplied by 9 percent) of the Medicare Part B covered professional service payments distributed in the form of payment adjustments to ASM participants and an estimated 1.35 percent (that is, 15 percent multiplied by

9 percent) retained by Medicare We refer readers to the regulatory impact analysis in section VII of this final rule for further discussion on the estimated impacts of these payment adjustments.

As with the exchange function discussed later in this section of this final rule, we view the important factors when specifying a ASM redistribution percentage to be-- (1) the number of ASM participants that receive a positive payment adjustment; (2) the marginal incentives for all ASM participants to make broad-based care quality improvements and reduce low-value care, and (3) the ability for ASM to demonstrate savings over the ASM test period. We intend for the proposed ASM redistribution percentage to appropriately balance these factors.

We analyzed the distribution of ASM payment adjustment factors using simulated final scores data, focusing on the full range of available ASM payment adjustment factors using a sample of likely ASM participants. We found that an 85 percent ASM redistribution percentage would achieve an appropriate distribution of the number of ASM participants that would receive positive and negative payment adjustments under the different exchange functions that we considered, as discussed later in this section of this final rule. We also found that an 85 percent ASM redistribution percentage under the proposed exchange function would achieve the desired magnitude of positive and negative ASM payment adjustment factors under the ASM risk level proposed for the 2027 ASM performance year.

We considered ASM redistribution percentages as high as 100 percent and as low as 60 percent. An ASM redistribution percentage of 100 percent would mean that the entirety of Medicare Part B covered professional service payments multiplied by the applicable ASM risk level would be distributed through ASM payment adjustment factors to ASM participants. We believe that ensuring a particular level of net savings through an ASM redistribution percentage less than 100 percent would help guarantee a particular level of Medicare Part B savings that would contribute to the net savings in total cost of care from provider behavioral effects that we hypothesize would occur as part of ASM as described in section III.C.1.(b) of this final rule.

We refer readers to the regulatory impact analysis in section VII. of this final rule for further discussion on the scale of ASM and its estimated financial impacts. We considered an ASM redistribution percentage as low as 60 percent because it would increase the potential for higher net savings on Medicare Part B payments and mirrors a similar rate used by SNF VBP Program (82

FR 36619 through 36621). In analyses, however, we found decreasing the ASM redistribution percentages below what we proposed (for example, to 60 percent or 75 percent) would result in an unfavorable distribution of negative and positive ASM payment adjustment factors that would not create the desired set of payment incentives to achieve ASM's goals.

We solicited comments on our proposed ASM redistribution percentage and alternatives considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters recommended eliminating the proposed 85 percent ASM redistribution percentage to calculate payment adjustments for ASM participants. Many commenters noted that the 15 percent withhold from the budget pool leads to Medicare savings through a forced reduction in Medicare Part B payments for all clinicians, even high performers. A commenter shared their belief that the ASM redistribution percentage results in the program being solely punitive. Commenters noted that neither HVBP nor MIPS relies on a redistribution percentage. Several commenters recommended ASM be budget neutral. A few commenters did not support the proposed redistribution percentage and noted a high standard of clarity and transparency is needed to ensure clinician understanding and trust. The commenters shared their belief that the ASM redistribution percentage may be perceived as an arbitrary reduction in payment and suggested that CMS specify how the funds contribute to program solvency, or are reinvested into beneficiary care in order to gain participant buy-in.

Response: We appreciate commenters for their feedback. We would like to clarify that, as proposed, ASM's payment approach would not lead to a forced reduction in Medicare Part B payments for all ASM participants. The proposed calculation of ASM payment adjustments relies on the ASM incentive pools, which are virtual incentive pools based on ASM participant's historic Part B payments for covered professional services, meaning that there is no prospective withhold of ASM participants' payments, such is done under some other CMS VBP programs. We would calculate ASM payment adjustments so that the expected net result of ASM's payment adjustments when applied during an ASM payment year (that is, the grand sum of Medicare Part B payments for covered professional services to ASM participants multiplied by their respective ASM payment multipliers) would be less than the amount

calculated for each ASM cohort's virtual incentive pool. This payment approach means that we expect ASM to achieve net savings to Medicare through the Part B adjustments, as well as through the hypothesized behavioral effects described in the evaluation section, section III.C.2.l, of this final rule. As there would be no respective withhold, ASM participants would continue to receive payment adjustments that range from the negative of the applicable ASM risk level and potentially up to the applicable ASM risk level on the positive end. We also note that MIPS and HVBP are required to be budget-neutral under each of the program's authorizing statutes. As an Innovation Center model under section 1115A(b) of the Act, ASM is not subject to the same budget neutrality requirement in its payment approach, but rather, must ultimately demonstrate statistically significant model savings. Ultimately, we believe that not redistributing the entirety of each cohort's incentive pool allows ASM to achieve the desired payment incentives while ensuring that the model meets its statutory requirement to generate savings.

Comment: A commenter noted that the proposed ASM redistribution percentage could be justified for a voluntary model, where participants elect to take risk with the hopes to perform highly and receive a positive payment adjustment, but not in a mandatory model.

Response: We appreciate the commenter for their feedback but disagree that the ASM redistribution percentage is only justifiable under a voluntary model by virtue of a voluntary model participant's choice to take on downside risk. Other mandatory Innovation Center models introduced downside risk from the beginning of the model, such as the Transforming Episode Accountability Model (TEAM). Under TEAM's payment methodology, we withhold a portion of the benchmark price for TEAM episodes based on a discount factor; we later reconcile actual spending against the episode's target price after the end of a TEAM episode to determine the net payment reconciliation amount owed to or owed by TEAM participants as described at § 512.550.

Comment: A few commenters did not support the proposed ASM redistribution percentage and instead recommended a five percent redistribution percentage. A few commenters shared their belief that a redistribution percentage of no more than 5 percent is comparable to other value based and bundled payment programs and improves financial incentives for ASM participants. A commenter recommended that CMS could supplement savings to the Trust Fund through improved comparison of ASM EBCM savings in ASM with MIPS.

Response: We appreciate the commenters for their suggestion on an alternative ASM redistribution percentage. Based on how we define the ASM redistribution percentage, we interpret their suggestion to mean 95 percent and not 5 percent. As discussed earlier in this section of this final rule, we believe that the use of a redistribution percentage less than 100 percent allows ASM to achieve its desired payment incentives to drive care improvements while achieving net savings to Medicare. Further, as we discussed in the CY 2026 proposed rule (90 FR 32610), in analyses, we found that an 85 percent ASM redistribution percentage would achieve an appropriate distribution of the number of ASM participants who would receive positive and negative payment adjustments under the different exchange functions that we considered, as discussed later in this section of this final rule. We also found that an 85 percent ASM redistribution percentage under the different considered exchange functions would achieve the desired magnitude of positive and negative ASM payment adjustment factors under the ASM risk level proposed for the 2027 ASM performance year. We interpret the commenter's suggestion to compare ASM and MIPS EBCM performance to identify savings for the Medicare Trust Fund to be related to ASM's evaluation approach rather than a modification to ASM's payment methodology. From an evaluation perspective, improvements in EBCM scores over time could identify cost savings. Within our evaluation, we believe that it would be more appropriate to compare EBCM performance over time among ASM participants and against a pool of clinicians with similar characteristics as ASM participants, which would likely include clinicians participating in MIPS.

Comment: A few commenters suggested alternative approaches to generate savings in ASM, through improvements in efficiency, higher quality care and reduction in avoidable utilization without the need for withholding incentive funds.

Response: We appreciate the commenters for their suggestions on alternative approaches to generate savings under ASM. We believe that the collective set of incentives introduced by ASM will drive efficiency improvements, improved quality of care, and reductions in some avoidable or unnecessary services that would collectively drive savings. We refer readers to section III.C.2.l of this final rule for further discussion on how we plan to evaluate ASM against these hypothesized savings.

After consideration of public comments, we are finalizing the proposed ASM redistribution percentage at 85 percent as proposed at § 512.750(c)(1)(iii).

(c) Exchange Function

An exchange function translates a participant's final score into a payment adjustment. The type of exchange function used can influence: (1) how many participants receive positive, neutral, or negative payment adjustments; and (2) the size, or magnitude, of the payment adjustment percentage that corresponds to a given performance score. The choice of an exchange function ultimately contributes to creating an optimal set of incentives by setting the distribution and size of payment adjustments.

We proposed at § 512.750(c)(1)(ii) to use a logistic exchange function to translate final scores into ASM payment adjustment factors that would distribute each ASM incentive pool to their respective ASM participants through ASM payment adjustment factors that result in net negative, neutral, or positive payment adjustments.

In our view, important factors when adopting an exchange function include: (1) the percentage of ASM participants that would receive positive payment adjustments compared to those that would receive negative payment adjustments and (2) the magnitude of the maximum positive and negative net payment adjustment. We believe that ASM would be most effective at encouraging ASM participants to improve the quality of care that they provide to Medicare beneficiaries if ASM participants can earn positive adjustments through high performance across ASM's performance categories but also face some level of downside risk through possible negative payment adjustments. We also believe that the magnitude of negative and positive adjustments must create a strong incentive for improving care related to ASM's targeted chronic conditions. The choice of an exchange function, and the specific parameters of the chosen exchange function, can create different distributions of ASM payment adjustment factors, ASM payment multipliers, and net payment adjustments based on the final scores of ASM participants in each ASM cohort.

In the Quality Payment Program, CMS uses a linear exchange function to translate MIPS eligible clinicians' final scores into MIPS payment adjustment factors relative to an annually determined performance threshold so that the program is budget neutral (89 FR 62199). Under the Hospital VBP Program, CMS uses a linear exchange function to translate a hospital's Total Performance Score into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY (76 FR 26531 through 26534). We refer readers to the Hospital VBP Program Final Rule

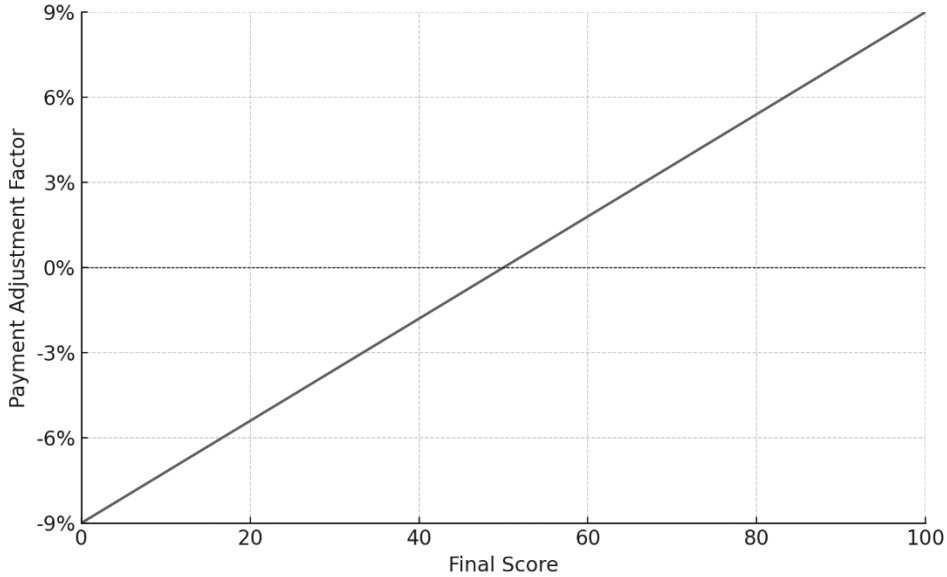
(76 FR 26531 through 26534) for detailed discussion of the Hospital VBP Program's exchange function, as well as responses to public comments on this issue. Under the SNF VBP Program, CMS uses a logistic function to translate a SNF's performance score into an incentive payment multiplier (82 FR 36616 through 36619). The SNF VBP Program also considered a cube exchange function during its notice-and-comment rulemaking related to the SNF VBP Program exchange function (82 FR 36616 through 36619). We refer readers to the SNF VBP Program final rule (82 FR 36616 through 36619) for detailed discussion on the SNF VBP Program's exchange function and responses to public comments on this issue.

Using the exchange functions that other Medicare VBP programs use or considered using while determining their payment methodology, we considered three exchange functions for use in ASM's payment methodology: (1) linear, (2) logistic, and (3) cube. The equations and graphs of the different exchange functions displayed in the remainder of this section of this final rule are illustrative. We note that the actual exchange functions' forms and slopes would vary depending on the distributions of final scores and wish to emphasize that we present these representations solely for the reader's clarity as we discuss our exchange function policy.

The linear function is a simple, steadily increasing function ranging from zero to one hundred (Figure B-D1). A linear exchange function would provide ASM participants the same marginal incentive to continually improve performance of their final score. The linear exchange function we considered had the following formula, where x_i is an ASM participant's final score:

$$f(x_i) = \frac{x_i}{100}$$

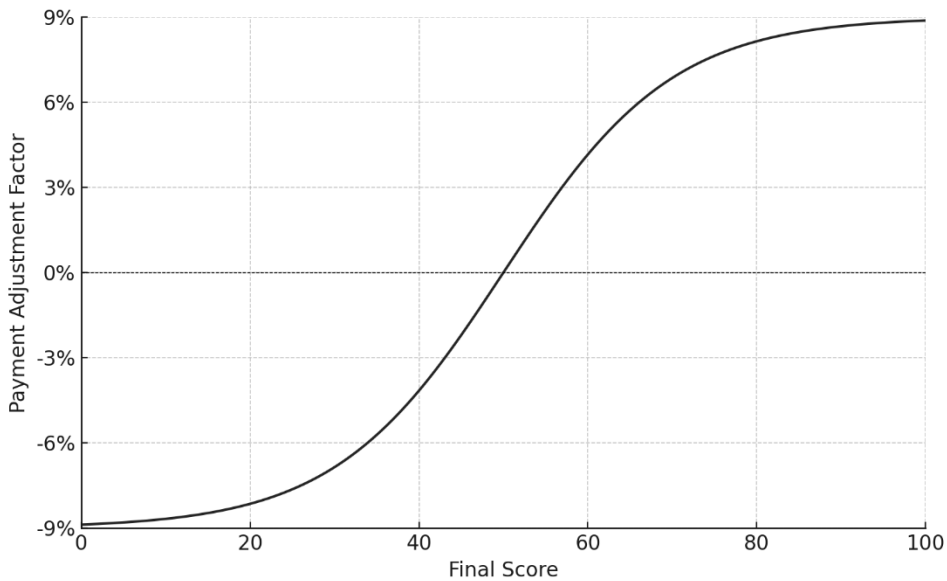
FIGURE B-D1: ILLUSTRATIVE LINEAR EXCHANGE FUNCTION



The logistic function is an S-shaped curve ranging between zero and one hundred with an inflection point at a specified midpoint (Figure B-D2). The S-shaped curve would mean that participants with scores within the bottom end of the distribution would receive similar payment adjustments and participants at the top end of the distribution would receive similar payment adjustments to one another. There would be more variation in the resulting payment adjustments for those participants with final scores in the middle of the distribution. The logistic exchange function we considered had the following formula, where x_i is an ASM participant's final score, x_0 represents the function's midpoint:

$$f(x_i) = \frac{1}{1 + e^{-0.1(x_i - x_0)}}$$

FIGURE B-D2: ILLUSTRATIVE LOGISTIC EXCHANGE FUNCTION

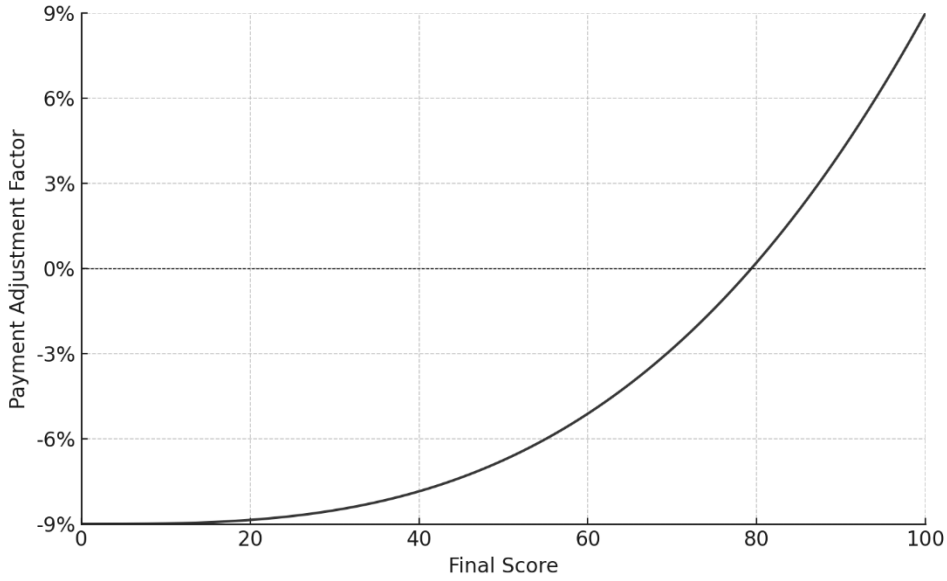


For the logistic exchange function, we considered values of the function's midpoint (that is, x_0 in the earlier formula) set at: (1) 50, which represents the midpoint between the zero to 100 point range that an ASM participant could achieve in their final score; (2) the annual median final score in the ASM performance year for each ASM cohort, and (3) the annual mean final score in the ASM performance year for each ASM cohort. The functional form of the logistic function when centered at 50 points would mean that those ASM participants with final scores within the top 25 percent and the bottom 25 percent of final scores would receive relatively similar ASM payment adjustment factors. However, setting the midpoint at the median or mean final score could help to achieve a more balanced distribution between ASM payment adjustment factors that result in net positive or net negative payment adjustments.

The cube function exponentially increases between zero and one hundred (Figure B-D3). The cube functions means that the incentive to improve performance increases more dramatically at the top end of the score distribution, meaning that a one-point difference in final score at the top end would result in a bigger difference in payment adjustment than the same one-point difference at the lower end of the final score distribution. The cube exchange function we considered had the following formula, where x_i is an ASM participant's final score:

$$f(x_i) = \left(\frac{x_i}{100}\right)^3$$

FIGURE B-D3: ILLUSTRATIVE CUBIC EXCHANGE FUNCTION



We analyzed these three exchange functions using simulated final score data. For the logistic exchange function, we used a midpoint of the median final score within each ASM cohort (see discussion on the logistic function's midpoint earlier in this section of this final rule). We simulated final scores by simulating each of the four ASM performance category scores using informed distributions for measures and the proposed scoring policies for each ASM performance category (see the regulatory impact analysis in section VII of this final rule for further information on our simulation methods). Our modeling ensures that the estimated ASM payment adjustment factors and ASM payment multipliers for each ASM cohort resulted in net payment adjustments that equaled the total ASM incentive pool for the applicable ASM cohort. We evaluated the distribution of ASM payment adjustments factors that resulted from each function (that is, the number and proportion of each ASM cohort that received net negative and positive payment adjustments). We also evaluated descriptive statistics (for example, mean, median, minimum, maximum) of the resulting ASM payment adjustment factors and ASM payment multipliers from each function. We also considered the distribution of ASM payment adjustment factors and ASM payment multipliers by specific ASM participant characteristics, such as small practices.

In our analysis, we found that linear and logistic exchange functions produced relatively similar distributions of ASM participants who would receive net positive payment adjustments, whereas more ASM participants would receive net positive payment adjustments under the cube function. Comparatively, the steadily increasing linear exchange function would mean that there would be a more even distribution of ASM payment adjustment factors across the distribution of final scores. Under the cube function, fewer ASM participants would receive net positive payment adjustments.

We found that setting the logistic function midpoint at the median or mean final score for each ASM cohort produced a maximum ASM payment adjustment factor that exceeded the maximum ASM payment adjustment factor under the linear exchange function (we refer readers to the discussion of the logistic function's midpoint earlier in this section of this final rule). That is, adjusting the logistic function midpoint to a value around the mean or median final score of each ASM cohort would increase the maximum net positive payment adjustment while producing a more even distribution between net positive and negative payment adjustments. The cube function produced the highest maximum ASM payment adjustment factor. All the exchange functions had the same maximum negative ASM payment adjustment factor because the ASM risk level would determine the maximum net negative payment adjustment.

When we compared the median ASM payment adjustment factor produced under each exchange function, we found that the logistic exchange function would produce the highest median net payment adjustment followed by the linear exchange function and then the cube exchange function. The cube exchange function would allow those ASM participants that achieve the highest final scores to achieve high ASM payment adjustment factors but would mean that ASM participants with final scores near the median final score would receive potentially lower ASM payment adjustment factors.

Based on the results of this analysis, we believe that the logistic exchange function would be best suited to achieving the appropriate distribution of ASM payment adjustment factors at the appropriate level of magnitude.

We recognize that using the same exchange function from other CMS programs would help interested parties that use these programs' payment information across care settings better understand ASM's payment methodology. Both the Hospital VBP program and the Quality Payment Program use some form of a linear exchange function in their payment methodologies. Three key program aspects that facilitate the use of a linear exchange function are a program's number of measures, measure weights, and correlation across program measures. These three aspects mean that there is less chance for a single required measure to skew scores into a non-normal distribution, meaning that it would be appropriate to use a linear exchange function for these programs (82 FR 36618). When first established, the SNF VBP Program relied on a single performance measure to determine performance scores. This approach meant that the distribution of performance scores could have been easily skewed, which could have resulted in

an undesired distribution of incentive payments (82 FR 36618). The SNF VBP Program has since added up to 9 measures by which it can assess performance and has retained use of a logistic exchange function (88 FR 53276 through 53304). In our analysis, we found that simulated final scores among likely ASM participants could be skewed due to the potential directional correlation between measures across ASM's performance categories; for example, an ASM participant who performs well on one required quality measure may perform well across other quality measures. The potential for a skewed final score distribution and the use of a linear exchange function could result in an undesired distribution of ASM payment adjustment factors. For these reasons, we believe that the logistic exchange function would be more appropriate for the purposes of ASM's payment methodology.

We solicited comments on our proposal to use a logistic exchange function with midpoint set at the median final score for each ASM cohort to translate final scores into ASM payment adjustment factors. We also sought comments on the alternative exchange functions and specifications of each exchange function we considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed methodology of using the logistic exchange function to calculate payment adjustments for ASM participants as it would incentivize ASM participants for higher performance.

Response: We appreciate the commenter for their support of the proposed logistic exchange function.

Comment: A few commenters did not support the proposed use of the logistic exchange function to calculate payment adjustments for ASM participants, noting unfamiliarity with the method and concerns about its impact. Commenters expressed concern that the logistic exchange function may inappropriately amplify ASM payment adjustments, potentially resulting in disproportionate payments relative to the performance of ASM participants. For example, an ASM participant with performance scores slightly below the median may receive negative payment adjustments that are almost as large as ASM participants with much lower scores. A commenter noted that ASM payment adjustments are made relevant to other ASM participants, rather than compared to an objective benchmark, and that differences

in ASM payment adjustments would not be directly proportional to differences in ASM final performance scores.

Response: We appreciate the commenters for their feedback. We disagree that unfamiliarity with the logistic exchange function is a reason not to use it as we will provide ASM participants with resources and support so they understand the final payment approach before the first ASM payment year. We also disagree that use of the logistic exchange function would inappropriately create payments adjustments such that participants just below the median final score would receive negative payment adjustments at the same magnitude of participants with much lower scores. In fact, the logistic exchange function works to spread out the distribution of payment adjustments for those participants with final scores near the median final score, allowing for more differentiation in performance. Simultaneously, there is less variation in payment adjustments at the ends of the distribution of final scores as demonstrated by the flattening of the function as it approaches a final score of zero or 100 (see Figure B-D3). For example, there would be less variation in ASM payment adjustment factors between an ASM participant with a final score of 90 compared to one with a final score of 98 using a logistic exchange function. This characteristic of the logistic exchange function means that ASM participants who achieve a certain level of high performance would receive relatively similar adjustments, as would ASM participants whose final scores are at the bottom of the final score distribution. As it can be difficult to differentiate between small differences in performance at the extremes of a distribution, we believe that this feature of the logistic exchange function is advantage as it keeps those adjustments at extremes relatively similar. We refer readers to our discussion of why the logistic exchange function would help us better differentiate performance given the correlation we expect to see across measures in the quality ASM performance category in the CY 2026 PFS proposed rule (90 FR 326140). The commenter is correct that ASM's payment approach determines ASM payment adjustment factors by comparing final scores of ASM participants within each ASM cohort rather than compared to an objective benchmark. We refer readers to our discussion of why we decided not to use a predetermined performance threshold in ASM's payment approach in our response to comments in section III.C.2.f.(2) of this final rule.

Comment: A commenter recommended the alternative to use the median determined by the exchange function from a previous ASM performance year for comparing the performance of ASM

participants. The established and published median would allow ASM participants to determine the score at which they would avoid a negative ASM payment adjustment.

Response: We appreciate the commenters for their suggestion on using each ASM cohort's median final score from the previous ASM performance year in the logistic exchange function formula. Use of the median final score in the logistic exchange function does not determine the cutoff in final score that differentiates a positive ASM adjustment factor from a negative ASM payment adjustment factor. In other words, use of the median final score in the logistic exchange function does not force an even 50 percent distribution between ASM participants receiving positive and negative ASM payment adjustment factors. As we described in the CY 2026 PFS proposed rule, use of the median final score in the logistic exchange function would likely mean that more ASM participants would be likely to receive positive ASM adjustment factors compared to using a midpoint value of 50, which would represent the midpoint of possible final scores, or the mean final score (90 FR 32612). For these reasons, we do not believe that using a one-year lag of the median final score would provide additional benefit to ASM participants in calculating payment adjustments. We do intend to provide ASM participants with performance data of their ASM cohort around the time we release the ASM performance reports so that ASM participants would have this data to calibrate their performance during a given ASM performance year.

Comment: A few commenters supported the use of a linear exchange function to calculate payment adjustments for ASM participants, noting its familiarity for clinicians due to alignment with MIPS and the HVBP and the potential to reduce negative impacts to ASM participants.

Response: We appreciate the commenters for their feedback on the alternative linear exchange function that we considered. We understand that the use of a linear exchange function in MIPS would mean that many ASM participants may be familiar with it given that most ASM participants will have previously participated in MIPS. We do not agree that the use of a linear exchange function in HVBP would mean that more ASM participants would be familiar with a linear exchange function as we would not expect most ASM participants to be familiar with the HVBP payment methodology given that program focuses on hospitals and not individual clinicians or clinician groups. As we discussed in the CY 2026 PFS proposed rule (90 FR 32613), we found that the logistic exchange function has two benefits

over the linear exchange function under the same ASM risk level and ASM redistribution percentage in our modeling. First, more ASM participants would be likely to receive positive ASM payment adjustments under the proposed logistic exchange function compared to a linear exchange function. Second, the median ASM payment adjustment factor would be higher under the logistic exchange function than under the linear exchange function. We believe that more ASM participants receiving potentially higher ASM payment adjustment factors would be advantageous to ASM participants while creating the desired incentives.

After consideration of public comments, we are finalizing use of the proposed logistic exchange function as proposed at § 512.750(c)(1)(ii).

(d) Notification of ASM Payment Adjustment Factors and ASM Payment Adjustment Multipliers to ASM Participants

As discussed in the CY 2026 PFS proposed rule (90 FR 32614), we proposed at § 512.750(e) to notify ASM participants of their ASM payment adjustment factor and ASM payment multiplier through the ASM performance report provided for each ASM performance year. As discussed earlier, we proposed at § 512.750(a) that the amount otherwise paid under Medicare Part B for covered professional services furnished by an ASM participant during an ASM payment year would be multiplied by the ASM payment multiplier determined based on an ASM participant's performance during an ASM performance year.

As discussed earlier in this section of this final rule, our proposed process currently draws from the processes and timelines by which the Quality Payment Program applies MIPS payment adjustments for MIPS eligible clinician as defined at § 414.1405(e). Aligning the timeline and processes with the Quality Payment Program application of MIPS payment adjustments would ensure operational consistency and minimize confusion for ASM participants that have previously participated in MIPS.

Given the time separation between the ASM performance year and the ASM payment year, there may be situations when an ASM participant's TIN affiliation changes between the ASM performance year and the corresponding ASM payment year. Accordingly, we proposed at § 512.750(f) that ASM payment adjustment factors and ASM payment multipliers would continue to apply to Medicare Part B covered professional services payments to ASM participants during an ASM payment year with

adjustments made depending on how TIN affiliations change after an ASM performance year and the end of the corresponding ASM payment year. In Table B-D10, we provide several illustrative scenarios and how our proposed policies discussed in this section of this final rule would affect the application of ASM payment multipliers in each scenario.

During an ASM payment year, we proposed at § 512.750(f)(1) that Medicare Part B professional service claims submitted by an NPI who is an ASM participant with a final score for an ASM performance year but under a TIN (1) that did not identify the NPI as an ASM participant for the applicable ASM performance year and (2) to which the NPI began assigning billing rights after the ASM performance year but before the end of the payment year would be adjusted using the ASM payment multiplier calculated for the ASM participant for the corresponding ASM performance year. For example, if an ASM participant identified by TIN-A/NPI bills Medicare under their original practice (TIN A) during an ASM performance year but begins billing Medicare Part B covered professional services claims under a new practice (TIN B) after the ASM performance year but before the end of the corresponding ASM payment year, then we would apply the ASM participant's ASM payment multiplier to Medicare Part B claims submitted by the NPI under the new practice (TIN -B/NPI). If the same ASM participant (TIN-A/NPI) from the above example also billed under TIN A during the same ASM payment year, we would adjust their Medicare Part B payments for covered professional services using the applicable ASM payment multiplier calculated for the ASM participant.

Our proposal means that we would not apply ASM payment multipliers to Medicare Part B claims submitted by TINs, other than the TIN identifying an ASM participant for an applicable ASM performance year and corresponding ASM payment year, to which the ASM participant assigned billing rights to before or during an ASM performance year. For example, if an ASM participant identified by TIN-A/NPI billed to TIN A and TIN B during the ASM performance year, then we would not apply the ASM payment multiplier to Medicare Part B claims submitted by the NPI under TIN-B during the corresponding ASM payment year. Our reasons for applying ASM payment multipliers to Medicare Part B claims to TIN/NPIs combinations created after the end of the ASM performance year and before the end of the corresponding ASM payment year would be to prevent application of multiple payment adjustments on Medicare Part B claims, such as MIPS payment adjustments, during an ASM payment

year. Building on the earlier example, in a given ASM performance year, an ASM participant (TIN-A/NPI) could be a MIPS eligible clinician under a different TIN/NPI combination (TIN-B/NPI) and receive a MIPS payment adjustment factor that would apply in the MIPS payment year that aligns with the corresponding ASM payment year. We would not want to interfere with the application of a MIPS payment adjustment factor to Medicare Part B claims billed under the TIN that identified the same NPI as a MIPS eligible clinician.

If we identify an NPI as ASM participants under multiple TINs and that NPI begins billing Medicare Part B claims under a new TIN (that is, neither of the original TINs) after the ASM performance year but before the end of the corresponding ASM payment year, then we proposed at § 512.750(f)(2) to adjust Medicare Part B covered professional service payments submitted by the NPI under the new TIN using the highest of all ASM payment multipliers received for all TIN and NPI combinations that identified the NPI as multiple ASM participants for the corresponding ASM performance year. While we believe that there would be few instances where a single NPI would be identified as multiple ASM participants, we believe this policy would appropriately track accountability to the NPI under a new TIN while reducing complexity by only applying on ASM payment adjustment multiplier.

TABLE B-D10: APPLICATION OF PAYMENT ADJUSTMENTS DURING AN ASM PAYMENT YEAR

Scenario	Payment Adjustment
An ASM participant receives a final score under TIN A for an ASM performance year and bills under TIN A in the corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN A/NPI combination using the ASM payment multiplier received under the TIN A/NPI combination.
An ASM participant receives a final score under TIN A for an ASM performance year and begins billing under TIN B after the end of the ASM performance year but before the end of corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN B/NPI combination using the ASM payment multiplier received under the TIN A/NPI combination.
An ASM participant receives a final score under TIN A for an ASM performance year but bills under TIN B during the corresponding ASM payment year. The ASM participant billed under TIN B before or during the ASM performance year.	The ASM participant would not receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN B/NPI combination using the ASM payment multiplier received under the TIN A/NPI combination.
An NPI is considered an ASM participant and receives a final score under TIN A and TIN B for an ASM performance year and continues to bill under TIN A and TIN B in the corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN A/NPI combination using the ASM payment multiplier received under TIN A/NPI combination and payment adjustments under TIN B/NPI combination using the ASM payment multiplier received under the TIN B/NPI combination.
An NPI is considered an ASM participant and receives a final score under TIN A and TIN B for an ASM performance year but begins billing only under TIN C after the ASM performance year but before the end corresponding ASM payment year.	The ASM participant would receive a payment adjustment on Medicare Part B covered professional services claims during the applicable ASM payment year under their TIN C/NPI combination using the higher of all ASM payment multipliers received under TIN A/NPI or TIN B/NPI combinations.

Our proposals closely linked the ASM participants' performance during an ASM performance year to the ASM payment multiplier. These policies would also ensure that ASM participants who qualify for net positive payment adjustments keep them, even if they change TINs by the start of the ASM performance year. For those who have a net negative payment adjustment, this proposal would also ensure ASM participants would remain accountable for their performance. As discussed earlier in this section of this final rule, our proposals would also prevent interference with the application of MIPS

payment adjustment factors if the NPI identifying the ASM participant was a MIPS eligible clinician under a different TIN/NPI combination during the same ASM performance year/MIPS performance period.

We based our proposed approach on sub-regulatory guidance issued by the Quality Payment Program on how MIPS payment adjustment factors follow MIPS eligible clinicians if they change their TIN affiliation after a MIPS performance period (81 FR 77330, 85 FR 84917 through 84919, and 86 FR 65536).[294] Like MIPS, our proposal for ASM tracks accountability to the ASM participant regardless of their specific TIN affiliation at the time we would apply ASM payment multipliers to an ASM participant's Medicare Part B covered professional services payments during an ASM payment year.

We solicited comments on our proposed approach to notify and apply ASM payment multipliers to Medicare Part B covered professional services payments during an ASM payment year. We also sought comment on how ASM payment multipliers would be applied to Medicare Part B covered professional services payments for ASM participants whose TIN affiliations change after an ASM performance year and before the end of a corresponding ASM payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that CMS clarify how the payment adjustment is applied, specifically if adjustments are applied to all Medicare Part B payments or those payments specific to episodes.

Response: We appreciate the commenters for their feedback. We clarify that we would apply ASM payment multipliers to all Part B payments for covered professional services to ASM participants during an ASM payment year. This clarification aligns with our policy for the application of payment adjustments as proposed in the CY 2026 PFS proposed rule.

Comment: Several commenters recommended that the ASM payment adjustments be applied only to the services related to the ASM episodes, and not to all Medicare Part B services, representing unrelated services delivered to other types of patients. A commenter expressed concern that applying the

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[294] https://qpp.cms.gov/resources/document/21ee9d76-a002-4f5d-b228-3a99b32aa7dc.

payment adjustment to all Medicare Part B services further compounds the financial risks of all ASM participants, including those who see a relatively low volume of patients with ASM targeted chronic conditions representing only a fraction of their practice. A commenter noted that applying payment adjustments to all Medicare Part B services could discourage clinicians from providing care to chronic heart failure and low back pain patients, due to potential negative impacts of low ASM performance scores on their payments for all other conditions.

Response: We appreciate the commenters for their feedback. We disagree with the commenter who believes applying the adjustment to all Part B services would discourage clinicians from providing care to beneficiaries with ASM's targeted chronic conditions. We believe that our participant eligibility criteria appropriately identify specialists that provide care to a higher volume of beneficiaries with ASM's targeted chronic conditions. As the model focuses on specialists, we would expect that most of the Part B payments to ASM participants would be directly related to ASM's targeted conditions, meaning that it would be appropriate to adjust all Part B covered professional services payments. Adjusting all Part B payments for covered professional services provides a stronger financial incentive to improve performance compared to only adjusting payment for selected services. Further, because ASM participants who would otherwise be required to participate in MIPS will be waived from MIPS requirements, only adjusting a portion of Part B payments for covered services related to ASM's targeted chronic conditions would mean that some payments would not be adjusted. In a hypothetical situation where only some Part B covered professional services payments are adjusted under ASM, allowing for simultaneous participation in ASM and MIPS would create undue burden and undermine the model test. Therefore, we believe it is appropriate to adjust all Part B covered professional service payments under ASM to create the right set of financial incentives to achieve ASM's objectives.

Comment: A commenter recommended that CMS increase transparency by using a designated payment code or clear identifier for applying the ASM payment adjustments. The commenter noted that the absence of a distinct code makes it challenging for providers to track and reconcile payments accurately and recommended the use of a designated payment adjustment code or a consistent remittance advice indicator specific to ASM payment adjustments.

Response: We appreciate the commenters for their feedback. We do not believe that it is

necessary for ASM participants to use a designated payment code in order for us to adjust payments. As described in our response to comments in this section of this final rule, we would apply ASM payment multipliers to all Part B payments for covered professional services to ASM participants during an ASM payment year, meaning that a separate payment code would be unnecessary and create an unnecessary burden.

Comment: A commenter did not support the use of an ASM performance report for sharing the payment adjustment information with participants and stated their concerns on significant delays in receiving MIPS performance results and payment adjustments. The commenter noted that introducing a high volume of individual reporting could further exacerbate delays at CMS and impact financial planning and performance feedback cycles for ASM participants.

Response: We appreciate the commenters for their feedback on the proposal to provide ASM payment adjustment factors and multipliers to ASM participants through the ASM performance report. We intend to release the ASM performance reports in an appropriate timeframe to mitigate concerns that delays could impact financial planning and performance feedback cycles for ASM participants.

Comment: A commenter suggested CMS clarify how payments adjustments are calculated and applied to ASM participants that change their TIN mid-year.

Response: We appreciate the commenter's request for clarification on policies related to TIN changes in the middle of an ASM performance year or ASM payment year. Based on our finalized policies at § 512.710(c), we note that ASM participants who change TINs during an ASM performance year must notify us of the change; after we approve of the change, the ASM participant will no longer be subject to the model requirements for that ASM performance year. Accordingly, the ASM participant will not receive a final score and will not have their Part B covered professional services payments adjusted in the corresponding ASM payment year. We refer readers to section III.C.2.c.(3).(ii) of this final rule for further discussion of this policy. Should the ASM participant change TINs during an ASM payment year, then the application of the participant's ASM payment multiplier under the new TIN depends on when the participant begins billing under the new TIN. If the ASM participant began assigning billing rights to the new TIN after the applicable ASM performance year but before the end of the corresponding ASM payment year, then we would continue to adjust payments under the new TIN using the participant's

ASM payment multiplier for the remainder of the applicable ASM payment year. We refer readers to Table B-D10 for examples of how this provision would be implemented under different scenarios.

Comment: A commenter recommended CMS implement tools for real-time reporting and payment adjustment monitoring, streamline dispute and correction workflows, and clearly define rules for resolving conflicts when clinicians report through multiple channels or receive inconsistent scoring between group and individual performance.

Response: We appreciate the commenters for their feedback on developing tools to allow ASM participants to report data in real time and monitor payment adjustments. At this time, we do not envision that real-time data reporting would be feasible for ASM. We also believe that the simplicity of the application of ASM payment multipliers to Part B covered professional service payments during an ASM payment would allow an ASM participant to monitor their payment adjustments. We note that we are not allowing ASM participants choice in how they report data (that is, as an individual and as a group) for a given ASM performance year, so there is no need to develop rules for resolving such reporting conflicts. Our finalized policies related to data submission at § 512.720 also describe how we will manage multiple data submissions from an individual ASM participant. We refer readers to section III.C.2.d.(1) of this final rule for further discussion on the data submission procedures and requirements.

After consideration of public comments, we are finalizing our proposed provisions related to notification of ASM participants of their payment adjustment factors and multipliers as proposed at § 512.750(e). We are also finalizing our proposed provision on how TIN changes after an ASM performance year but before the end of the corresponding ASM payment year affects application of ASM payment multipliers as proposed at § 512.750(f).

g. Timely Error Notice Process

We believe that it is necessary to have a process by which ASM participants may appeal the ASM performance report. However, the standard CMS claims appeals process submitted through a MAC would not lead to timely resolution of disputes for the purposes of ASM because MACs and other CMS officials would not have timely access to beneficiary attribution data. Therefore, we proposed waving the requirements of section 1869 of the Act specific to claims appeals for purposes of testing ASM. The ASM error notice process is specific to ASM and distinct from the standard CMS appeals procedures set forth

under section 1869 of the Act. We note that ASM participants would still be subject to the same limitations on review as stipulated at § 512.170.

We proposed at § 512.755(a) to permit ASM participants to submit a timely error notice regarding the calculations contained within the ASM performance report if the ASM participant believes an error occurred in calculations due to data quality or other issues, or if the ASM participant believes an error occurred in calculations due to misapplication of methodology. We proposed at § 512.755(b) that if an ASM participant believes the ASM performance report contains a calculation error, then the ASM participant would be required to submit a timely error notice documenting the suspected calculation error within 30 calendar days of issuance of the ASM performance report. We also proposed that CMS may specify different requirements for the form, manner, or deadline for submission of the error notice. If the ASM participant does not provide such timely error notice error in accordance with the timelines and processes specified by CMS, then we proposed at § 512.755(b)(1) that the ASM performance report would be deemed final and the ASM participant would be precluded from later contesting those elements of the ASM performance report for that performance year. Additionally, we proposed that only an ASM participant may submit a written timely error notice according to the provisions at proposed § 512.755(b)(2).

The proposed 30-day window to review and appeal CMS calculations aligns with the length of time we have finalized for submitting appeals in other mandatory Innovation Center models, such as TEAM and the Increasing Organ Transplant Access (IOTA) Model.

We acknowledge that the Quality Payment Program allows MIPS eligible clinicians to request a targeted review within 60 days of the closing of the data submission period. As explained in the 2016 Quality Payment Program Final Rule (81 FR 77353), section 1848(q)(13)(A) of the Act describes the required review process for MIPS as "targeted" and "informal," and does not warrant a second level of review or appeals. Under MIPS, all decisions under the targeted review process are final.

We considered an appeal window that conforms with MIPS, however, a 60-day timeframe would not be appropriate for ASM, as it would not provide sufficient time to generate final ASM payment adjustment factors and ASM payment multipliers before the applicable ASM payment year begins, given the process outlined in § 512.190 of the Standard Provisions—which offers the ASM participant the

opportunity to request two additional levels of appeal, including a final review by the CMS Administrator. If an ASM participant elects to go through all levels of appeal available to them, this would be a lengthy process that must conclude by December 1, when CMS must submit final payment adjustment factors to the MACs for the subsequent payment year. Therefore, because of the two additional levels of appeal, CMS is unable to offer ASM participants a lengthier period to review their initial calculations.

We proposed at § 512.755(c) that if CMS receives a timely notice of a calculation error, we will issue an initial determination in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. We note that CMS would reserve the right to an extension of the time for providing its initial determination upon written notice to the ASM participant.

If an ASM participant disagrees with CMS' initial determination and wishes to dispute the results of the initial determination, under proposed § 512.755(d), the ASM participant or CMS may request a reconsideration by following the reconsideration review process described in the standard provisions at § 512.190.

We solicited comment on our proposed timely error notice process for ASM appeals at § 512.755 as well as alternatives considered.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter acknowledged the proposed process for ASM participants to receive a timely error notice, allowing them to review their ASM performance report and submit an appeal to dispute any errors or miscalculations. However, the commenter expressed concern that requiring ASM participants to submit a request to review errors within 30 days of receiving the performance report may limit their ability to conduct a thorough review. Alternatively, another commenter suggested that CMS allow ASM participants to submit an error notice within 60 days of receiving the ASM performance report. The commenter noted that this timeline aligns with the MIPS review process and could help address the limitations of conducting a thorough review under the proposed 30-day window.

Response: We appreciate the commenters for their feedback. We recognize the importance of allowing ASM participants the opportunity to thoroughly review their performance report. As previously

discussed, we considered several possible timely error notice timelines during model development (including the MIPS 60-day review window). Due to the multi-step process required for calculating the ASM incentive pool, in conjunction with other internal CMS processes to ensure MACs can process ASM participant claim adjustments for the corresponding payment year, we cannot extend the 30-day deadline for ASM participants to submit timely error notices.

Comment: A commenter recommended that CMS implement a preview period for ASM participants to review their attribution assignments, as well as a formal appeals period to correct errors in specialty designation and attribution. The commenter shared their belief this approach would allow clinicians to exclude non-managing episodes and protect them from ASM payment adjustments.

Response: In reading the commenter's feedback holistically, it appears the commenter is requesting a period to review CMS' identification of a particular clinician as an ASM participant. Specialty designation and beneficiary attribution are two of the elements that CMS uses to identify whether a clinician is eligible to be an ASM participant. Per 42 USC1315a(d)(2), "the selection of organizations, sites, or participants to test those models selected" is precluded from administrative or judicial review. While an ASM participant may submit a request to CMS for unrefined Medicare Parts A, B, and D claims data used to determine ASM participant eligibility for an applicable ASM performance year, this data cannot be used to request review of a clinician's ASM participation status. Moreover, ASM identifies a clinician's specialty types from claims-based specialty codes, which use PECOS information self-reported by clinicians. Thus, if a clinician believes they should update their specialty designation, the clinician will need to follow instructions from PECOS on how to correct their specialty designation.

After consideration of public comments, we are finalizing the timely error notice process as proposed at § 512.755.

h. Waivers of Medicare Program Requirements

(1) Background

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. We proposed to waive ASM

participants from MIPS reporting and payment adjustments. We also proposed to waive certain telehealth restrictions to encourage greater flexibility with the use of telehealth services by ASM participants.

(2) MIPS Waiver

We believe it may be necessary and appropriate to provide flexibilities to clinicians participating in ASM. We proposed at § 512.775 to use the Innovation Center's statutory authority under section 1115A(d)(1) of the Act to waive all ASM participants from participation in MIPS for any ASM performance year / ASM payment year in which they meet the ASM participant eligibility criteria, unless otherwise specified at proposed § 512.710(a)(2). Our previous and current efforts in testing models where participants are judged against the performance of their peers, such as the SNF VBP Program and the HVBP Program, are likely to incentivize substantial improvements in cost savings and efficiency. We are building off existing mechanisms for payment adjustments of Medicare Part B claims found in MIPS. To maximize the effectiveness of these payment adjustments, we proposed to waive ASM participants from participation in MIPS. This waiver would ease the administrative burden, as ASM participants would be required to only report ASM performance category measures. The waiver would also prevent possible double-payment adjustments by ensuring ASM participants report their performance measures and receive payment adjustments through ASM alone. The MIPS waiver would only be available to ASM participants for the year(s) for which they are measured for performance under the model (that is, the ASM performance year). For example, if a clinician meets eligibility criteria for the model in CY 2027 and is measured for performance under the model for that year, the MIPS waiver applies to CY 2027 and the clinician is not required to participate in MIPS and be measured for performance under MIPS for that year. Yet, for any subsequent year that that clinician does not meet ASM eligibility criteria and is not measured for performance under the model, the MIPS waiver does not apply. The clinician must participate in MIPS and be measured for performance under MIPS if determined to be a MIPS eligible clinician for the applicable MIPS performance period.

We intend to promote as much longitudinal model overlap as possible and ensure maximum flexibility for ASM participants to join existing voluntary models, including Advanced APMs. Specialty care providers have been part of whole-person and primary care models, such as the Shared Savings Program, but the performance measures in those programs are less relevant to specialty care. ASM takes

the founding tenets for MVPs and goes further, allowing for like-to-like comparisons for all ASM participants by ensuring they are reporting on the same, clinically relevant measures.

For these reasons, we proposed to seek a MIPS waiver at § 512.775(a) for all ASM participants regardless of whether they have achieved Qualifying APM Participant (QP) status through another Medicare model or program.

We solicited comments on the proposed MIPS waiver for all ASM participants at § 512.775(a).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed policy waiving MIPS requirements for all ASM participants for any ASM performance year in which they meet ASM eligibility criteria. The commenters noted that exemption from MIPS would reduce duplicate reporting and administrative burden for clinicians.

Response: We appreciate the commenters for their support of the MIPS exemption for ASM participants for any ASM performance year in which they meet ASM eligibility criteria.

Comment: A few commenters supported the proposed policy waiving MIPS requirements for ASM participants who meet ASM eligibility criteria and offered additional recommendations. A commenter shared their belief that the MIPS waiver relieved reporting burden and recommended that the waiver apply to any ASM participant selected for a model year and remain in effect for the entire year. A few commenters recommended that CMS to apply the exemption by classifying the model as an advanced APM (AAPM) to enable ASM participants to meet QP thresholds, be exempt from MIPS, and receive the higher PFS conversion factor update.

Response: In response to the commenter who recommended applying the MIPS waiver to any ASM participant selected for a model year and allowing the waiver to remain in effect for the entire year, we believe the proposed policy already does this. We proposed to define "ASM performance year" as a 12-month period beginning on January 1 and ending on December 31 of each year during the first 5 calendar years of ASM test period. Thus, any ASM participant for a given ASM performance year will be exempt from MIPS for the entire corresponding calendar year.

Regarding the comments recommending classification of ASM as an Advanced APM to enable

QP status determination for ASM participants, we appreciate the commenters' questions and feedback about whether ASM would qualify as an Advanced APM. We will consider if there are ways for ASM to qualify as an Advanced APM in the future based on the Advanced APM requirements as defined at § 414.1415.

Comment: A commenter did not support the proposed policy waiving MIPS requirements for ASM participants, expressing concern that annual ASM eligibility determinations could require clinicians to participate in MIPS, and recommended CMS allowing ASM participants to opt-in to both MIPS and ASM.

Response: We appreciate the commenter's feedback. An ASM participant who meets ASM eligibility criteria for a given ASM performance year is exempt from MIPS for that entire ASM performance year and must report for ASM performance categories. During model development, we identified the MIPS exemption for mandatory ASM participants as a critical piece of the model test. Specifically, if we allowed ASM participants to opt-in to both MIPS and ASM, then this significantly raises the risk of a double-payment adjustment to the ASM participant's claims during the payment year.

After consideration of public comments, we are finalizing the MIPS waiver at § 512.775(a) as proposed.

(3) Telehealth

(a) Background

We expect that the proposed ASM design features would lead to greater interest on the part of ASM participants caring for ASM beneficiaries in furnishing services to beneficiaries in their home or place of residence. ASM would create new incentives for comprehensive care management for beneficiaries, including early identification and intervention regarding changes in health status. Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. Under the longstanding statutory payment requirements, telehealth services must be furnished to a beneficiary located in one of the originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the geographic requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the

Medicare Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all the following other requirements for payment: (1) the service must be furnished via an interactive telecommunications system, (2) the service must be furnished to an eligible telehealth individual, and (3) the individual receiving the services must be in an eligible originating site. For most telehealth services, this requires the beneficiary to be located at an originating site that is in certain, mostly rural, areas, and in a setting that is a health care facility.

During the PHE for COVID-19, CMS used emergency authority under section 1135(b)(8) of the Act to waive these requirements to allow beneficiaries to be located in an originating site in any geographic area and in any setting, including the home of the beneficiary. Congress has enacted several laws that temporarily extend these flexibilities beyond the PHE. Most recently, the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119-4) amended section 1834(m)(4)(C)(iii) of the Act to extend these originating site flexibilities through September 30, 2025. Absent Congressional action, beginning October 1, 2025, the statutory limitations that were in place for Medicare telehealth services prior to the COVID-19 PHE will retake effect for most telehealth services. These include geographic and location restrictions on where the services are provided.

When all these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS website at https://www.cms.gov/medicare/coverage/telehealth/list-services. Under section 1834(m)(4)(F)(ii) of the Act, we have an annual process to consider additions to and deletions from the list of telehealth services.

Some literature suggests certain beneficial telehealth technologies, which enable health care providers to deliver care to patients in locations remote from providers, are being increasingly used to complement face-to-face patient-provider encounters to increase access to care, especially in rural or

underserved areas.[295] In these cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We note that certain covered professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode-based payment models, such as TEAM and the Comprehensive Care for Joint Replacement Model (CJR) model, participants were permitted to use telehealth waivers that applied to two provisions:

● CMS waived the geographic site requirements under 1834(m)(4)(C)(i)(I) through (III) of the Act which allowed telehealth services to be furnished to eligible telehealth individuals when they are located at an originating site at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements.

● CMS waived the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act which allowed the eligible telehealth individual to not be in an originating site when the otherwise eligible individual is receiving telehealth services in their home or place of residence.

These telehealth waivers allowed providers and suppliers furnishing services to ASM beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and allowed the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe similar telehealth waivers would be essential to maximize the opportunity to improve the quality of care and efficiency for ASM.

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[295] Azizi Z, Broadwin C, Islam S, et al. Digital Health Interventions for Heart Failure Management in Underserved Rural Areas of the United States: A Systematic Review of Randomized Trials. *J Am Heart Assoc*. 2024;13(2):e030956. doi:10.1161/JAHA.123.030956.

(b) Telehealth Waivers

Specifically, like the telehealth waivers in TEAM and the CJR model, we proposed at § 512.775(b) to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiving of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim that is not excluded from the proposed episode (see section III.C.2.c.(3).(b). of this final rule) could be furnished to an ASM beneficiary, regardless of the beneficiary's geographic location. Under ASM, this waiver would support care coordination and increasing timely access to high quality care for all ASM beneficiaries, regardless of geography. Additionally, we proposed waiving the originating site requirements of sections 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we proposed at § 512.775(b)(2) to waive the requirement only when telehealth services are being furnished in the ASM beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services that is not excluded from the proposed episode definition (see section III.C.2.c.(3).(b). of this final rule) could be furnished to an ASM beneficiary in their home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are in that setting. Section 1834(m) of the Act provides for the conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the

location of the practitioner is unspecified. To create a mechanism to report E/M services accurately, TEAM and the CJR model used specific sets of HCPCS G-codes to describe the E/M services furnished to the model beneficiaries in their homes via telehealth. We considered whether establishing ASM-specific G-codes would serve a distinct purpose to the model. Upon review of existing G-codes for services provided via telehealth, we identified concerns with administrative burden and duplicative codes. Thus, we proposed to allow ASM participants to bill established G-codes.[296]

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service originated in the beneficiary's home). Finally, ASM participants furnishing a telehealth service to an ASM beneficiary in his or her home or place of residence would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished under the telehealth waivers only during the episode.

We plan to monitor patterns of utilization of telehealth services under ASM to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with ASM participants.

We solicited comments on the proposed waivers with respect to telehealth services at § 512.775(b).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed ASM telehealth waiver for the geographic site requirements, which currently limit telehealth payment to services provided by ASM participants. A commenter specifically noted that the waiver would enable Medicare beneficiaries to access telepsychiatry, regardless of rural or urban status.

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[296] https://www.cms.gov/medicare/coverage/telehealth/list-services.

Response: We appreciate the commenters for their support.

Comment: A few commenters generally supported the proposed telehealth waiver for the geographic site requirements, noting that that these waivers would provide quality and cost-effective care to patients at their preferred locations. The commenters recommended that CMS monitor the use of waivers to ensure access, quality, beneficiary experiences and cost, to prevent overutilization and inappropriate billing. Other commenters acknowledged that the existing evaluation and management codes do not adequately reflect telehealth services and appreciated CMS using established HCPCS G-codes in ASM. A few commenters shared their belief that CMS not creating ASM specific billing codes helps reduce burden and maintain consistency for clinicians. One commenter shared their belief that the HCPCS G-codes would help track visit rates, wait times, clinical outcomes, and utilization among disadvantaged groups. A commenter recommended that telehealth waivers for ASM participants should not be restricted beyond what is permitted by law.

Response: We appreciate the commenters for their support. ASM relies upon existing CMS mechanisms to monitor the use of telehealth and the permitted range of telehealth waivers.

Comment: A commenter recommended CMS providing incentives for ASM participants for telehealth services provided at a patient's home.

Response: We appreciate the commenters for their feedback. At this time, ASM is not considering incentives for telehealth services.

Comment: A commenter recommended CMS expanding telehealth flexibilities beyond ASM to reflect virtual care delivery, use this waiver authority to remove copays and other payment barriers for both telehealth and Remote Patient Monitoring (RPM)/Remote Therapeutic Monitoring (RTM) services, which are relevant to heart failure and low back pain.

Response: We refer the commenter to section III.C.2.k.(1) of this final rule, which discusses how ASM participants may use of the CMS-sponsored model safe harbor for patient incentives.

After consideration of public comments, we will finalize § 512.775(b) as proposed.

i. Extreme and Uncontrollable Circumstances (EUC) Policy

Events may occur outside the purview and control of the ASM participant that may affect their performance in the model. We proposed at § 512.780 to apply a variation of the EUC policy for MIPS

eligible clinicians (83 FR 60081), but with notable differences around scoring. Currently, MIPS has three mechanisms to adjust scoring MIPS performance categories due to external circumstances that may impact a MIPS eligible clinician's ability to report during a given performance year: (1) the MIPS automatic EUC policy;[297] (2) the MIPS EUC Exception; and (3) the MIPS Promoting Interoperability Performance Category Hardship Exception.[298] The latter two require affected MIPS eligible clinicians to submit an application to MIPS for consideration before being granted the exception. The MIPS Automatic EUC Policy, however, grants the exception to any MIPS eligible clinician located in a CMS-designated region affected by EUC, such as a Federal Emergency Management Agency (FEMA)-designated major disaster or an HHS-determined public health emergency. The exception eliminates the need for an application to request reweighting one or more MIPS performance categories.

We proposed to adopt at § 512.780 a modified version of the MIPS Automatic EUC Policy. We would use the same triggering events from the MIPS Automatic EUC Policy, such as federal disaster and/or public health emergency declarations, as the basis for determining whether an ASM participant may be automatically exempted from submitting ASM performance category data for an ASM performance year during which they were impacted by the EUC. If the ASM participant's CBSA or metropolitan division that we use to determine ASM participant eligibility (as described at § 512.710(e)(5)) is within an area identified by CMS, under § 414.1380(c)(2)(i)(A)(8), as having been affected by extreme and uncontrollable circumstances,, then the ASM participant would be exempted from the requirement to submit ASM performance category data, as described at proposed § 512.720. We proposed at § 512.780(c)(1) that ASM participants who qualify for the exemption and do not submit ASM performance category data that meet the requirements at § 512.720 would not receive a final score and would receive an ASM payment adjustment factor that results in a neutral payment adjustment for the applicable ASM payment year. We proposed at § 512.780(c)(2) that ASM participants who qualify for the exemption but still submit ASM performance category data that meet the requirements at § 512.720 would be scored according to the methodology described at proposed § 512.745. We also considered using claims data to determine whether an ASM participant furnishes services in a Federal disaster area or

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[297] https://qpp.cms.gov/resources/document/3579730b-0891-4491-b880-eb21da631b15.
[298] https://qpp.cms.gov/mips/exception-applications.

in an area in which HHS has declared a public health emergency. However, we believe that using the same methodology to determine whether a clinician furnishes services in a mandatory geographic area as part of the ASM participant eligibility criteria would ensure consistency across geographic determinations used for EUC-related exemptions.

Furthermore, we recognize the external impact of circumstances outside of the ASM participants' control, such as large-scale cyberattacks and other emergencies outside of those identified in the previous paragraphs. We proposed at § 512.780(b)(1) and (2) to allow CMS to determine, based on information known to the agency prior to the beginning of the relevant ASM payment year, that data for an ASM participant are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents, including third-party intermediaries. We proposed to notify ASM participants of CMS' decision on the existence of circumstances as proposed at § 512.780(b)(1) and the impact of these circumstances upon scoring methodology for affected ASM participants. We also proposed to grant CMS discretion in the form and manner of the notice to ASM participants.

We considered adopting an application-based process for EUC exceptions like the MIPS provisions described at § 414.1380(c)(6). However, we believe that any hardships outside of those contemplated at proposed § 512.780(a) and (b) that renders an ASM participant unable to report on ASM performance categories for quality, improvement activities, or Promoting Interoperability, would likely result in the ASM participant being unable to bill claims for that ASM performance year as well. Accordingly, we believe that ASM participants in these circumstances would likely not meet the case minimums for quality and cost measures in their respective ASM performance categories (as proposed at §§ 512.725(g) and 512.730(d)) and would, therefore, be subject to a neutral payment adjustment for the applicable ASM payment year. For example, if the ASM participant does not have 20 EBCM episodes identified in claims data for the impacted ASM performance year, then the ASM participant would not receive a final score and would be subject to an automatic neutral payment adjustment. However, in this scenario, since CMS is unable to determine whether the ASM participant meets the 20 EBCM episodes for the given ASM performance year until all claims for that ASM performance year have been completed, the ASM participant is encouraged to submit as much data as they are able to for all other ASM performance measures.

We considered whether an ASM participant affected by the circumstances at proposed § 512.780(a) or (b) who chooses to report ASM performance category data would be subject to a lower risk level as described at § 512.745(a)(3). Applying a differential risk level for some ASM participants could skew the calculation of ASM payment adjustment factors for all ASM participants depending on how many ASM participants are impacted by the identified circumstances. Instead of adjusting the ASM participant's risk level, we believe it would be preferable for ASM participants not to receive a final score, which would result in an automatic neutral payment adjustment.

We solicited comments on the proposed provisions at § 512.780, as well as the alternatives that we considered.

We did not receive public comments on this provision, and therefore, we are finalizing the proposed provisions at § 512.780 as proposed.

j. Data Sharing

Under this model, we aim to incentivize ASM participants to engage in care redesign efforts to improve quality of care and reduce Medicare FFS spending for ASM beneficiaries. As discussed in the CY 2026 PFS proposed rule (90 FR 32619), we expect ASM participants to work toward independently tracking their own data through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of health care items and services. However, we proposed certain data sharing requirements in § 512.760 to assist ASM participants in this process and in meeting the model objectives.

We proposed at § 512.760(d) to provide certain aggregate data that has been de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 CFR 164.514(b), for the purposes of helping ASM participants understand their progress towards improving upon the model's performance metrics. We noted that any aggregate data provided in advance of an ASM performance report for an ASM performance year would not be a guarantee of the ASM participant's final score or ASM payment adjustment factor.

Additionally, as with other mandatory Innovation Center models such as TEAM and IOTA, we proposed to provide certain beneficiary-identifiable data to ASM participants regarding the ASM

beneficiaries under their care, upon request and execution of a data sharing agreement. We stated that we anticipate ASM participants would use this data to assess their treatment patterns and overall care plans and to identify room for improvement under the model or conducting other "health care operations" under the HIPAA Privacy Rule, 45 CFR 165.501. Specifically, subject to the limitations discussed in this final rule, and in accordance with applicable law, including the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164), we proposed at § 512.760(b) that CMS may offer an ASM participant an opportunity to request certain Medicare beneficiary-identifiable data. We proposed that CMS would share this beneficiary identifiable data with ASM participants on the condition that the ASM participants and other individuals or entities performing functions or services related to the ASM participant's activities observe all relevant statutory and regulatory provisions regarding: (1) the appropriate use of data; and (2) the confidentiality and privacy of individually identifiable health information, and comply with the terms of the data sharing agreement proposed at § 512.760(e).

Moreover, we stated that we recognize that an individual clinician generally may not be a covered entity. However, the participant clinicians are likely part of a covered entity and therefore are subject to the HIPAA Rules.

We proposed at § 512.760(f) that ASM participants must allow Medicare beneficiaries to request restrictions on sharing data, consistent with 45 CFR 164.522(a). We also proposed at § 512.760(b)(4) that, for the beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with an ASM participant.

We requested comment and feedback on our proposed policies at § 512.760(a) to make certain beneficiary-identifiable data available to ASM participants upon execution of an ASM data sharing agreement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended that CMS create a portal with episode lists and attribution rosters to reduce clinician burden.

Response: We intend to develop an online tool for ASM participants to access data from CMS at

§ 512.760. We appreciate the commenter's suggestion regarding episode lists and will consider these items when developing the ASM participant portal. However, we remind the commenter that ASM beneficiaries are defined as "a Medicare FFS beneficiary who is being treated by an ASM participant for a targeted chronic condition." Therefore, we do not intend to maintain an up-to-date ASM beneficiary attribution roster, although an ASM participant may request beneficiary-identifiable data for their ASM beneficiaries using the data sharing process described at § 512.760(b). Accordingly, we expect that data for their ASM beneficiaries produced under the data sharing process would represent a snapshot of ASM beneficiaries.

Comment: A commenter stated that there are gaps in current CMS data regarding objective pain levels for seniors, women, and individuals with low back pain, and expressed the belief that without this data, CMS, primary care physicians, and specialists may struggle to determine the appropriate volume of low back pain procedures and surgeries. The commenter recommended that CMS provide objective pain data through specialized databases, enabling better decision-making and ensuring appropriate care for patients with pain-related conditions.

Response: We appreciate the commenter's feedback on the availability of pain data to inform clinical decision-making and how access to that data may vary at the practice level. While custom technical solutions, like the databases suggested by the commenter, may offer some clinicians expanded access to pain data or a more efficient process to analyze such data within their patient populations, we also believe that many clinicians would already have access to such data within their practice's medical record systems and EHRs. Accordingly, we currently do not have any plans to use or refer ASM participants to external databases containing objective pain data, although ASM participants are welcome to refer to such databases to support their performance within the model.

Comment: A few commenters encouraged CMS to publish industry data on preliminary performance as early as possible in order for eligible clinicians to prepare for the new model. A commenter recommended CMS to clarify the types of data that CMS could include (for example, benchmarks on performance, cost measures) and suggested that clinicians could also benefit from reviewing Claim and Claim Line Feed (CCLF) information.

Response: We appreciate the commenters for providing this feedback. At this time, we do not

intend to publish any data related to ASM participants' performance prior to the start of the model. However, we refer the commenters to provisions at § 512.760(b). Once they have been identified as ASM participants, clinicians may use the process outlined at § 512.760(b) through (e) to request raw claims data, which may include CCLF data, used to determine ASM participant eligibility for an applicable ASM performance year, or data for ASM beneficiaries who triggered an applicable EBCM episode with the ASM participant during the applicable ASM performance year.

Comment: A few commenters recommended that CMS create safeguards to account for data fluctuations and ensure timely data sharing that is needed for clinical interventions. The commenters expressed the belief that the 2-year lag time between performance and payment would make it challenging for clinicians to correct course and achieve associated savings. Another commenter recommended that CMS prioritize sharing transparent, real-time performance data and clear benchmarks when developing its model to empower practices to monitor progress, adjust interventions, and engage in continuous improvement. A commenter recommended that CMS provide specialists with both aggregated and claims-level data on a monthly basis to understand their own performance. The commenter also recommended that CMS provide aggregated benchmark data on other ASM specialists' performance to increase competition among clinicians.

Response: We appreciate the commenters for their feedback. We would like to clarify that participants will receive their ASM performance report, which contains information on their annual performance in each ASM performance category and their resulting ASM payment adjustment factor and multiplier, in the calendar year following the end of an ASM performance year and before the corresponding ASM payment year begins. Based on the time allowed for participants to report data and the time required for us to analyze the reported data, we believe that our timeline for sharing performance feedback is appropriate and that a more accelerated performance feedback timeline may not be possible. We note that most quality measures are CQM or eCQM collection types, which would allow participants to track their performance on these measures during an ASM performance year. As we have noted throughout this section of this final rule, we intend to consider sharing data with participants that could allow them to understand their performance on claims-based quality and cost measures during an ASM performance year, as well as other potential utilization and spending data related to ASM's targeted

chronic conditions. While the data shared will adhere to the data sharing provisions finalized in this section of this final rule, we intend to provide further updates on the scope and content, including release cadence, of the shared data prior to the start of the first ASM performance year. Regarding benchmarks, we refer readers to section III.C.2.d.(2).(i).(ii) of this final rule for discussion of our quality measure benchmarking provisions and to section III.C.d.(3).(g).(ii) of this final rule for discussion of our cost measure benchmarking provisions.

Comment: A commenter stated that it agreed with the ability of ASM participants to request data on their attributed patients in order to track their overall care and recommended that CMS work with electronic medical record groups to find effective ways to access CMS claims data which can then be shared directly with the ASM participants through a patient's electric medical record and reduce costs. A commenter encouraged CMS to leverage its recently announced data strategy to establish a health technology ecosystem and thus further support the integration of PRO-PMs, functional status measures, and other quality metrics across care settings, reducing administrative burden, enabling seamless data sharing between specialists and PCPs, and facilitate tracking longitudinal outcomes.

Response: We appreciate the commenters' suggestions for leveraging health information technology to lower administrative burden and boost care coordination. We note that ASM already integrates a PRO-PM and several eCQMs into its ASM quality performance category measures. As we consider future ASM Promoting Interoperability performance category measures and develop ASM's data sharing capabilities, we will continue exploring how health information technology can be used to promote seamless data sharing between specialists, PCPs, and beneficiaries.

After consideration of public comments, we are finalizing at § 512.760(b) through (e) as proposed with the clarifying modification regarding the removal of "gender" from proposed § 512.760(c)(3).

(1) Data Provided to ASM Participants

(a) Legal Authority to Share Beneficiary-Identifiable Data and Applicability to ASM Data Sharing Processes

As discussed in the CY 2026 PFS proposed rule (90 FR 32619), we believe that an ASM participant may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating its performance, conducting quality assessment and improvement activities, conducting

population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of "health care operations" under the HIPAA Privacy Rule, 45 CFR 164.501.

We recognize there are sensitivities surrounding the disclosure of beneficiaries' individually identifiable health information, and that several laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits the disclosure. Here, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS to ASM participants so they can carry out "health care operations" that fall within the first and second paragraphs of the definition of the term as defined at 45 CFR 164.501. We proposed to make ASM participants accountable for quality and cost outcomes during an applicable ASM performance year. We stated that we believe it is necessary for the purposes of this model to offer ASM participants the ability to request certain raw beneficiary-identifiable Medicare claims data that CMS used to determine ASM participant eligibility for an applicable ASM performance year, as well as for the beneficiaries who trigger an EBCM episode with the ASM participant during the applicable ASM performance year. ASM participants would only receive data for the ASM beneficiaries who are their patients. We noted that we believe these data would constitute the minimum information necessary to enable ASM participants to understand care spending patterns, appropriately coordinate care, and target care strategies toward ASM beneficiaries.

Under the HIPAA Privacy Rule, covered entities (defined in 45 CFR 160.103 as health plans, health care providers that conduct certain transactions electronically, and health care clearinghouses) may only use or disclose protected health information (PHI), a subset of individually identifiable health information, as permitted or required by the HIPAA Privacy Rule, without the individual's authorization. The Medicare FFS program, a "health plan" function of the Department, is subject to the HIPAA Privacy Rule limitations on the use or disclosure of PHI without an individual's authorization. ASM participants are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they electronically transmit any health information in connection with one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. ASM participants are clinicians

who are either covered entities themselves, or they are part of a covered entity. We believe that the proposed disclosure of beneficiary-identifiable data under ASM would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for "health care operations" purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operation's purposes if both covered entities have or had a relationship with the subject of the PHI being requested, the PHI pertains to such relationship, and the PHI disclosure is for a "health care operations" purpose listed within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes "conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines," and "population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination." The second paragraph of the definition of health care operations includes "evaluating practitioner and provider performance" (45 CFR 164.501).

We proposed at § 512.760 that, subject to having an ASM data sharing agreement in place, an ASM participant may request from CMS certain beneficiary-identifiable claims for ASM beneficiaries under their care. Under the ASM data sharing agreement, we proposed at § 512.760(b)(5)(i) and (ii) to allow CMS to share data with an ASM participant which includes unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data used to determine ASM participant eligibility for an applicable ASM performance year, as well as unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data for ASM beneficiaries who trigger an episode with the ASM participant during the applicable ASM performance year. ASM participants would use the data on their patients to evaluate the performance of the ASM participant and other providers and suppliers, such as clinicians with whom the ASM participant may have entered into a CCA that furnished services to the patient, conducts quality assessment and improvement activities, and conducts population-based activities relating to improved health for their patients. When done by or on behalf of an ASM participant that is a covered entity, these data uses would qualify as "health care operations" under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. This encompasses the anticipated uses of the beneficiary-identifiable data by an ASM participant so that such uses would be permissible under the HIPAA Privacy

Rule. Moreover, when done by or on behalf of a covered entity, these are covered functions and activities that would qualify as "health care operations" under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501, thus encompassing the anticipated uses of the beneficiary-identifiable data by an ASM participant and that such uses would be permissible under the HIPAA Privacy Rule. Moreover, we stated, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of "health care operations."

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities or business associates must make "reasonable efforts to limit" the PHI that is used, disclosed, or requested to the "minimum necessary" to accomplish the intended purpose of the use, disclosure, or request (45 CFR 164.502(b)). Thus, we stated that ASM participants must limit their beneficiary-identifiable data requests to the minimum necessary, as selected from the proposed data elements identified at § 512.760(c), to accomplish the intended purpose of the use, disclosure, or request. We stated that the proposed minimum necessary data elements include, but are not limited to:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Sex.[299]
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax identification number.
- National provider identifier.

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[299] As originally proposed, §512.760(c)(3) stated "Sex or Gender." We intended to remove the term "gender" to align with current Administration directives, including Executive Order 14168 (Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government).

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when Federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

"Routine uses" are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the Federal Register about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We stated that, for the purposes of ASM as proposed, we believe that the proposed data disclosures are compatible with the purposes for which the data discussed in this rule was collected, and, thus, would not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records "routine use" is in place prior to making any disclosures. The systems of records from which CMS would share data are the Medicare Integrated Data Repository (IDR), the Common Working File, Medicare Provider Enrollment, Chain, and Ownership System (PECOS), the Enrollment Database (EDB), and the Part D Event (PDE) File. We stated that we believe that the proposed data disclosures are compatible with the purposes for which the data discussed in the CY 2026 PFS proposed rule were collected and may be disclosed in accordance with the routine uses applicable to those records (90 FR 32620).

We proposed at § 512.760 that we would share the ASM beneficiary-identifiable lists and data with ASM participants who have submitted a formal request for the data. Under our proposal, the request must be submitted on at least an annual basis in a manner and form specified by CMS. The request also would need to identify the data being requested and include an attestation that (1) the ASM participant is requesting this beneficiary-identifiable data as a HIPAA covered entity, or as part of a HIPAA covered entity, and (2) the ASM participant's request reflects the minimum data necessary for the ASM participant to conduct activities that are described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501. In addition, we proposed that ASM participants who request this data must have a valid and signed ASM data sharing agreement in place, as described in more detail later in this

section of this final rule. We proposed at § 512.760(b) that we would make available beneficiary-identifiable data for ASM participants to request for purposes of conducting activities described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries. We noted that we believe that access to beneficiary identifiable claims data would improve care coordination between ASM participants and other health care providers.

We also proposed at § 512.760(b)(2)(ii) that ASM participants limit the request for beneficiary-identifiable claims data to Medicare beneficiaries who have been seen by ASM participants for an ASM targeted chronic condition, and who did not request to restrict sharing their claims data with the ASM participant, as proposed at § 512.760(f)(1). Finally, we proposed that CMS would share beneficiary identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's activities, comply with all applicable laws governing the use of data and the privacy and security of individually identifiable health information and the terms of the ASM data sharing agreement proposed at § 512.760(e)(1).

(b) Medicare Beneficiary Opportunity to Request Restrictions on Data Sharing

We proposed at § 512.760(f)(1) that ASM beneficiaries would be notified about the opportunity to request restrictions on sharing claims data with an ASM participant, in accordance with 45 CFR 164.522. Recognizing the administrative burden associated with such restrictions, however, we noted that under 45 CFR 164.522(a)(1)(iii), covered entities are not required to agree to such a restriction unless the request fulfills the conditions set forth at 45 CFR 164.522(a)(1)(vi). Furthermore, we proposed that Medicare beneficiaries may not decline to have the aggregate, de-identified data proposed in § 512.760(d) shared with ASM participants. We also noted that, in accordance with 42 U.S.C. 290dd-2 and its implementing regulations at 42 CFR part 2, we would not share beneficiary identifiable claims data relating to the diagnosis and treatment of substance use disorders under this model.

We stated that we recognize this policy is distinct from the data sharing policy in IOTA and other Innovation Center models.[300] We considered aligning the data sharing provisions with IOTA but decided

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[300] In the CY 2026 PFS proposed rule (90 FR 32621), we originally stated we recognized the proposed policy was distinct from the data sharing policy in IOTA and "other voluntary Innovation Center models." We recognize this may have caused some confusion, as IOTA is not a voluntary model. We have revised the language for clarity.

to propose alignment with HIPAA requested data restriction provisions because they are less administratively burdensome on providers. We requested comments and feedback on our proposed policies at § 512.760(f) to enable ASM beneficiaries to request restrictions on data sharing with their treating ASM participant. We also requested comment and feedback on whether ASM should align its data sharing policies with existing Innovation Center models or retain its existing proposed structure, which is based on HIPAA requirements at 45 CFR 164.522.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support CMS' proposal to allow beneficiaries to decline data sharing and expressed the belief that such decisions are beyond clinicians' control yet could negatively impact and burden clinicians. The commenter recommended that CMS emphasize the benefits of data sharing to beneficiaries and clearly communicate that no action is required for them to remain included.

Response: We appreciate the commenters for the feedback. We recognize that our proposed policy to base the ASM data sharing opt-out policy on HIPAA requirements in 45 CFR 164.522 may have caused confusion, as it was intended to reduce (not increase) the burden on clinicians whose patients request to restrict data sharing under ASM. We also acknowledge the importance of ASM participants obtaining comprehensive data for as many ASM beneficiaries as possible to be able to conduct certain health care operations activities in connection with the model. Thus, we are not finalizing the proposed provisions at § 512.760(f) or the other references to paragraph (f) in that section in this rule. We note that removing these provisions aligns ASM data sharing with certain other Innovation Center Models, such as TEAM, which do not require participants to offer their beneficiaries the opportunity to decline claims data sharing. We also note that our decision not to finalize these proposed ASM provisions has no impact on existing HIPAA Privacy Rule requirements for covered entities or on individuals' rights to request privacy protection for PHI under 45 CFR 164.522.

Comment: A commenter encouraged CMS to align the ASM data sharing restriction provisions with stronger data sharing policies regarding PHI data sharing that are used in other Innovation Center models. The commenter also suggested CMS to develop consumer-friendly language around beneficiary protections related to PHI for use by ASM participants and expressed the belief ASM participants should

provide this information to beneficiaries orally or using American Sign Language during an in-person visit.

Response: We appreciate the commenters' suggestions. ASM's data sharing policies were developed to align with the HIPAA Privacy Rule requirements under 45 CFR 164.522. As noted above, we are not finalizing the proposed provisions in paragraph (f) because they may have caused confusion and because we recognize the importance of enabling ASM participants to obtain comprehensive data for as many ASM beneficiaries as possible for their health care operations efforts under the model. However, we will continue to consider whether a data sharing opt-out policy would be appropriate for ASM and may address this issue in future rulemaking. That said, we are finalizing a number of other ASM data sharing policies that protect beneficiary data and align with other Innovation Center models. For example, ASM participants may only obtain beneficiary-identifiable data upon execution of a data sharing agreement and the data requested must be the minimum necessary to accomplish the ASM participants' intended purpose. Additionally, ASM participants and any downstream recipients of the data are bound to the same terms and conditions to which the ASM participant is bound, per the data sharing agreement requirements at § 512.760(e), and are required to adhere to all applicable laws.

Regarding the commenter's suggestion that ASM participants provide information on beneficiary protections related to PHI in person and either orally or using American Sign Language, we appreciate the feedback and will encourage ASM participants to deliver information regarding ASM data sharing in the manner that is tailored to their patient population's unique needs.

After consideration of public comments, we are not finalizing the provisions at proposed § 512.760(f) regarding the ability of ASM beneficiaries to request to restrict data sharing. In addition, we are removing the corresponding references to paragraph (f) in paragraphs (a) and (b)(2)(ii), and redesignating the proposed paragraph (g) regarding data custodians to be in paragraph (f).

(c) Aggregated Data Sharing

We proposed at § 512.760(d) to deliver certain aggregate data that has been de-identified in accordance with the HIPAA Privacy Rule, 45 CFR 164.514(b), for the purposes of helping ASM participants understand their progress towards improving upon the model's performance metrics. Such aggregated, de-identified data could include, when available, claims-based cost, utilization, and quality

data. Cost and utilization data could include fields such as average Medicare FFS (Part A and Part B) expenditure per beneficiary, the top diagnosis codes for beneficiaries the ASM participant is seeing, or hospital admission and readmission rates. Quality data could include preliminary measure rates for the claims-based measures in each ASM measure set. We stated that the data would support ASM participants in analyzing care provided to their Medicare patients and their efforts to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. We stated that we were considering providing these two forms of performance feedback at regular intervals, allowing insights into trends that could result in improved model performance and beneficiary care. We sought comments on the elements, cadence, and format of this claims-based performance aggregated data and how it could be most beneficial to ASM participants in improving quality and reducing costs.

We noted that any aggregate data provided in advance of an ASM performance report for an ASM performance year would not be a guarantee of the ASM participant's final score or ASM payment adjustment factor. Since this data would be de-identified according to the HIPAA Privacy Rule requirements and would not contain any protected health information (PHI) or personally identifiable information (PII), this aggregate data would be provided to ASM participants regardless of whether they have executed an ASM data sharing agreement with CMS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters recommended that CMS provide ASM participants with timelier feedback than proposed with regard to information covering cost, utilization, quality signals, and performance. The commenters recommended that CMS provide clinicians with monthly or quarterly ASM reports on what triggered episodes, to allow clinicians to better understand and improve cost effective care, prevent avoidable penalties, protect beneficiaries, and protect the Trust funds. Another commenter recommended that CMS provide user-friendly tools for eligible clinicians to track patient progression and comparative scoring as close to real-time as possible, as relying on CCLF files for analytics is impractical for most practices and increases provider burden related to the ASM.

Response: We appreciate this feedback. At this time, we have not identified the frequency with

which we would share aggregated data to ASM participants beyond the annual ASM performance report, which will contain information on a participant's final ASM performance category scores, final scores, and payment adjustment information for a given ASM performance year. We will take these suggestions under consideration as we determine how often we would share aggregated deidentified data that could help ASM participants understand their potential performance on select metrics relevant to ASM. We are exploring different avenues through which ASM participants could receive more frequent aggregated data to inform clinical decisions and to calibrate their performance within the model.

Comment: A commenter encouraged CMS to establish a mechanism to share data directly with health IT vendors to improve transparency into ASM participant eligibility and help vendors better support clinicians.

Response: We appreciate the commenter's suggestion. We are not currently contemplating making ASM data available to non-ASM participants, as we believe the proposed ASM data sharing policies are appropriate and sufficient. ASM participants may contract with health IT and other data vendors for operational support and share their data with the vendor, but the ASM participant and any such downstream recipients must comply with the data sharing agreement requirements at § 512.760(e).

After consideration of these public comments, we are finalizing the aggregated data feedback provision in § 512.760(d) as proposed.

(2) ASM Data Sharing Agreement

(a) General Requirement for Beneficiary-Identifiable Data

We proposed at § 512.760(e)(1) that if an ASM participant wishes to retrieve ASM beneficiary-identifiable data, the ASM participant would be required to complete, sign, and submit and thereby agree to the terms of, an ASM data sharing agreement with CMS on at least an annual basis. We proposed to define the "ASM data sharing agreement" in proposed § 512.705 as an agreement between the ASM participant and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the ASM participant under proposed § 512.760(e). We proposed that under the ASM data sharing agreement, the ASM participant would be required to comply with the limitations on the use and disclosure of PHI imposed by the HIPAA Privacy Rule, the applicable ASM data sharing agreement, and the statutory and regulatory requirements of ASM. We also proposed that the ASM data sharing

agreement would include certain protections and limitations on the ASM participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. We proposed at § 512.760(g) that a designated data custodian would be the individual(s) that an ASM participant would identify as responsible for ensuring compliance with all privacy and security requirements, including all applicable laws and terms of the ASM data sharing agreement, and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

As discussed in the CY 2026 proposed rule (90 FR 32622), we believe it is important for the ASM participant to first complete and submit a signed ASM data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the ASM participant. We stated that there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ASM participants would be further protected in an appropriate fashion.

We solicited public comment on our proposal at § 512.760(e) to require that the ASM participant agree to comply with all applicable laws and terms of the ASM data sharing agreement as a condition of retrieving beneficiary-identifiable data, and on our proposal that the ASM participant would need to submit the signed ASM data sharing agreement at least annually if the ASM participant wishes to retrieve the beneficiary-identifiable data.

We did not receive public comments on this proposal.

We are finalizing the provisions at § 512.760(e)(1) and the definition of "ASM data sharing agreement" § 512.705 as proposed.

(b) Content of the ASM Data Sharing Agreement

We recognize that ASM participants may already be required to comply with the HIPAA Privacy Security, and Breach Notification Rules "(HIPAA Rules") as covered entities themselves, or as employees or owners of HIPAA covered entities. However, since ASM participation is at the TIN-NPI level, we recognize that the TINs to which the ASM participants belong may be the covered entities, rather than the ASM participants themselves. Thus, as discussed in the CY 2026 PFS proposed rule (90 FR 32622), we proposed to include language allowing ASM data sharing agreements to be executed

between CMS and ASM participants or the covered entities that conduct HIPAA standard transactions on behalf of the ASM participants. We also proposed at §§ 512.760(e)(1)(i) through (v) to impose CMS-specific requirements within the ASM data sharing agreement to reinforce the Innovation Center's specific expectations and consequences for misuse, which is intended to protect the privacy and security CMS' beneficiary-identifiable data in the hands of ASM participants and any downstream recipients. We proposed that under the ASM data sharing agreement, ASM participants would agree to certain terms, including:

● Complying with the requirements for use and disclosure of this ASM beneficiary-identifiable data that are imposed on covered entities, as defined by 45 CFR 160.103, by the regulations at 45 CFR part 160 and part 164, subparts A and E, including but not limited to ensuring the data will not be used for purposes outside of conducting health care operations as defined at 45 CFR 164.501 and as permitted by 45 CFR 164.506(c)(4) on behalf of their ASM beneficiaries

● Complying with privacy, security, breach notification, and data retention requirements specified by CMS in the ASM data sharing agreement if CMS deems such requirements necessary to safeguard beneficiary data, in addition to applicable law, such as the HIPAA Privacy, Security, and Breach Notification Rules

● Contractually binding any and each downstream recipient of the ASM beneficiary-identifiable data, such as persons or entities performing functions or services related to the ASM participant's data sharing activities including those that meet the definition of a business associate as defined at 45 CFR 160.103 and non-ASM participant parties to CCAs described at § 512.771, to the same terms and conditions to which the ASM participant is itself bound in its ASM data sharing agreement with CMS as a condition of the business associate's receipt of the ASM beneficiary-identifiable data obtained by the ASM participant

● Acknowledging that if the ASM participant or any downstream recipient misuses or discloses the ASM beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the ASM data sharing agreement, CMS may do any or all of the following: deem the ASM participant ineligible to obtain ASM beneficiary-

identifiable data for any amount of time, or subject the ASM participant to additional sanctions and penalties available under applicable law.

● An ASM participant must comply with all applicable laws and the terms of the ASM data sharing agreement to obtain ASM beneficiary-identifiable data.

We proposed at § 512.760(e)(2) that CMS would share beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including business associates of the ASM participant as defined at 45 CFR 160.103 and non-ASM participant parties to CCAs described at § 512.771, comply with all relevant laws governing the use of data and the privacy and security of individually identifiable health information and the proposed terms of the ASM data sharing agreement.

We stated that we believe that those proposed terms for sharing beneficiary-identifiable data with ASM participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ASM participants would be further protected by the ASM participant, and any business associates of the ASM participant as defined at 45 CFR 160.103 and non-ASM participant parties to CCAs described at § 512.771, in an appropriate fashion. We noted that we have these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards for data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. We stated that these provisions would be in addition to any restrictions imposed by applicable law, such as the HIPAA Rules, and would not prohibit the ASM participant from making any disclosures of the data otherwise required by law.

We solicited public comments on the proposal at § 512.760(e)(2) to impose certain requirements in the ASM data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

We did not receive public comments on this provision, and therefore, we are finalizing this

provision at § 512.760(e)(2) as proposed.

k. ASM Beneficiary Incentives, Collaborative Care Arrangements (CCAs), and Applicability of CMS-Sponsored Model Safe Harbor at § 1001.952(ii)

(1) ASM Beneficiary Incentives

As part of CMS' commitment to empower patients to actively participate and be accountable for quality and whole health outcomes, we invited ASM participants to think outside the box with regards to physical and lifestyle factors that contribute to the ASM's targeted chronic conditions. We proposed at § 512.770(a)(1) through (8) to allow ASM participants the option of providing in-kind patient engagement incentives, so long as the following criteria are met:

● The incentive must be provided directly by the ASM participant or by an agent of the ASM participant under the ASM participant's direction and control to an ASM beneficiary who is an established patient of the ASM participant.

● The ASM participant must be solely responsible for any costs associated with the provision of the incentive, including but not limited to, the retail value of the item or services offered as the ASM beneficiary incentive.

● The item or service provided must be reasonably connected to medical care provided by the ASM participant to an ASM beneficiary for an ASM targeted chronic condition.

● The item or service must be a preventive care item or service or an item or service that advances a clinical goal for an ASM beneficiary by engaging the ASM beneficiary in better managing an ASM targeted chronic condition. ASM's clinical goals are centered around promoting preventive care through improved management of ASM targeted chronic conditions; empowering patients to actively participate and be accountable for quality and whole health outcomes; and facilitating meaningful and efficient coordination between specialists and PCPs to increase independent physician participation in value-based payment programs.

● The item or service must not be tied to the receipt of items or services outside the services furnished by the ASM participant to the ASM beneficiary.

● The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

● The availability of the items or services must not be advertised or promoted, except that an ASM beneficiary may be made aware of the availability of the items or services at the time the ASM beneficiary could reasonably benefit from them.

● The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.

● The totality of items or services, including technology as described at paragraph (b) of this section, provided to an ASM beneficiary may not exceed $1,000 in retail value for any one ASM beneficiary.

We envisioned this could take the form of remote patient monitoring devices such as blood pressure monitors or scales with or without the capability to send data to their providers, vouchers for healthier food options or meal planning, and promotions for regular physical activity such as gym memberships or classes. These are, however, just examples and are not inclusive of all options available to ASM participants who offer beneficiary incentives. To safeguard against potential fraud, waste, and abuse, however, we proposed to require limits on the retail value of offered items or services, when offered items must be retrieved from the ASM beneficiary, and when an ASM beneficiary becomes eligible for ASM beneficiary incentives. Specifically, due to the multi-use nature of technological items and devices, we proposed at § 512.770(b)(1) and (2) the following stipulations for technology that are provided to ASM beneficiaries:

● Items or services involving technology provided to a ASM beneficiary must be the minimum necessary to advance a clinical goal of the model as proposed at § 512.770(b), which are: promoting preventive care through improved management of ASM targeted chronic conditions; empowering patients to actively participate and be accountable for quality and whole health outcomes; and facilitating meaningful and efficient coordination between specialists and PCPs to increase independent physician participation in value-based payment programs.

● Items of technology exceeding $75 in retail value must remain the property of the ASM participant. However, upon the end of their care relationship with the ASM participant, that technology must be retrieved from the ASM beneficiary with documentation of the ultimate date of retrieval. The ASM participant must document all retrieval attempts. In cases when the item of technology is not able to

be retrieved, the ASM participant must determine why the item was not retrievable. If it was determined that the item was misappropriated, then the ASM participant must take steps to prevent future beneficiary incentives for that ASM beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement. If the provided technology breaks or is otherwise rendered unusable for its intended purposes, the technology must be retrieved from the ASM beneficiary with documentation of the ultimate date of retrieval. The ASM participant may replace the unusable unit with the same or similar technology, to the extent practicable, that meets the original requirements for the technology.

● In addition to the requirements on audits and record retention at § 512.135, we proposed at § 512.770(c)(1) through (4) that ASM participants who wish to offer ASM beneficiary incentives must also ensure documentation of the incentives distributed according to the following requirements:

● ASM participants must maintain documentation of items and services furnished as beneficiary incentives that exceed $75 in retail value.

● The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the date the incentive is provided and the identity of the ASM beneficiary to whom the item or service was provided.

● The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable.

- The ASM participant must retain and provide access to the required documentation.

We sought comment on the proposed parameters at § 512.770 for allowed ASM beneficiary incentives, especially regarding the practicality and feasibility of the requirements around items of technology.

Comment: A few commenters supported the proposal allowing ASM participants to choose in-kind patient engagement incentives for beneficiaries with heart failure and low back pain, noting that this approach would improve upstream chronic disease management, health outcomes, and care delivery. A few commenters shared their belief that the proposed incentives would encourage whole-person care and wellness, reduce disparities, and improve population health and engagement in heart health-related

prevention and management behaviors. A commenter supported the use of vouchers for healthier food options and meal planning and recommended that CMS clarify the methodology for attributing and applying the incentives. Another commenter supported the proposed $1,000 for in-kind incentives, noting that it would enable clinicians to provide meaningful patient engagement incentives.

Response: We appreciate the commenters for their support.

Comment: A commenter recommended that CMS consider financial incentives and provide resources to assist practices with integrating new patient-engagement tools. Another commenter recommended that CMS offer financial support to small, rural practices for providing beneficiary incentives, such as Wi-Fi-enabled scales and blood pressure cuffs.

Response: At this time, we do not intend to offer financial support for ASM participants who wish to provide beneficiary engagement incentives. The decision to offer beneficiary engagement incentives is determined by each ASM participant and is not a mandatory requirement for the Model. We do not believe direct financial incentives are appropriate to promote an optional feature of the Model. Any future considerations regarding this policy would be discussed in future notice-and-comment rulemaking.

Comment: A few commenters supported the proposed ASM beneficiary incentives and recommended that CMS offer additional support such as best practices and templates for contract and financing structures, and technical assistance to help ASM participants integrate digital tools and work with solution vendors.

Response: We appreciate the commenters for their feedback. As we continue to develop model operations, we will consider the suggestions regarding additional CMS support for beneficiary engagement incentives and, if applicable, inform ASM participants of their availability.

Comment: Several commenters offered recommendations to CMS on the types of ASM beneficiary incentives CMS should consider. A few commenters recommended that CMS include incentives for wearable health devices, noting they empower patients to manage their own health, provide predictive insights, deliver timely alerts, and integrate directly into patient care plans. Another commenter recommended that CMS publish a list of preferred, high-value digital tools to support treatment options for patients with low back pain and heart failure. A few commenters recommended that CMS should consider beneficiary incentives for promoting screening for food insecurity, referrals to a community- or

hospital-based program for food and nutrition assistance, memberships to fitness facilities, supervised exercise therapy, and Needs Navigation assistance.

Response: We appreciate the commenters for their feedback; however, we believe that ASM participants are best suited to identify the unique needs and preferences of their beneficiary population. Therefore, to ensure we do not unduly influence ASM participants or inadvertently stifle innovation, we decline to limit the types of beneficiary engagement incentives that ASM participants may offer.

Comment: A commenter acknowledged CMS providing an up to $1,000 incentive to provide non-cash benefits to patients and recommended that CMS provide guidance on what qualifies as a non-cash incentive, such as approved technology for coordination between the participating specialists and PCPs.

Response: We refer the commenters to the provisions at proposed § 512.770(a) and (b) for details on the requirements for beneficiary engagement incentives permitted in ASM. As previously discussed, we do not intend to perform preemptive reviews of the types of technology offered by ASM participants to their ASM beneficiaries. However, at § 512.135, the Federal Government, including CMS, HHS, and the Comptroller General, or their designee, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of ASM, including records of all patient engagement incentives offered to ASM beneficiaries.

After consideration of public comments, we are finalizing the regulations at § 512.770 as proposed.

(2) Collaborative Care Arrangements (CCAs)

To support the goals of ASM, we proposed to encourage ASM participants to enter into CCAs with primary care practices to further the ASM participant's performance in the improvement activities ASM performance category or advance the clinical goals of ASM.

To allow ASM participants greater flexibility when negotiating CCAs, we proposed at § 512.765(a) to make the CMS-sponsored model arrangements safe harbor at 42 CFR 1001.952(ii)(1) available to ASM participants when establishing CCAs so long as they comply with the requirements of that safe harbor and proposed § 512.771. We proposed at § 512.771(a) to require all CCAs to:

- Be in writing, signed by both parties, and containing the effective date of the CCA.

- Be exclusively between the ASM participant and the primary care practice with whom the ASM participant shares at least one established patient who is an ASM beneficiary.
- The arrangement must be entered into for the purpose of furthering the ASM participant's improvement activities or advancing at least one of ASM's three clinical goals proposed at § 512.771(b), which are: promoting preventive care through improved management of ASM targeted chronic conditions; empowering patients to actively participate and be accountable for quality and whole health outcomes; and facilitating meaningful and efficient coordination between specialists and PCPs to increase independent physician participation in value-based payment programs.
- Participation in a CCA must be voluntary and without penalty for nonparticipation.
- Both parties to the CCA must comply with all applicable statutes, regulations, and guidance, including without limitation: Federal criminal laws; the False Claims Act (31 U.S.C. 3729 et seq.); the anti-kickback statute (42 U.S.C 1320a-7b(b)); the civil monetary penalties law (42 U.S.C. 1320a-7a); and the physician self-referral law (42 U.S.C. 1395nn).
- The opportunity to enter into a CCA, and the amount of any payment or other remuneration under a CCA, must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the CCA or any other person.
- Any payment between parties set forth in a CCA must not exceed fair market value and must be determined in accordance with a methodology that is solely based on the purposes identified at paragraphs (b)(2)(i) and (b)(2)(ii) of this section.[301]
- Any payment or other remuneration set forth in the CCA must be solely between the parties to the arrangements. Any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.
- Both parties to the CCA must retain the ability to make decisions in the best interests of the ASM beneficiary, including the selection of clinicians, devices, supplies, and treatments.

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[301] There was an error in proposed § 512.771(a)(7), where the regulatory text stated, "Any payment or other remuneration between the parties set forth in a CCA must not exceed fair market value and must be determined in accordance with a methodology that is solely based on the purposes identified at paragraphs (b)(2)(i) and (ii) of this section." However, due to formatting changes, the referenced language was actually moved and thus refers to proposed (a)(3)(i) and (a)(3)(ii).

- The CCA must not induce any party to reduce or limit medically necessary services to any Medicare beneficiary, or reward the provision of items and services that are medically unnecessary.
- ASM participants must maintain contemporaneous documentation, in accordance with § 512.135, regarding all CCAs to which they are a party.
- The CCA must stipulate that any non-ASM participant party is considered a downstream recipient for CMS data sharing purposes, and must require the non-ASM participant party to comply with applicable data sharing requirements at proposed § 512.760.
- Any non-ASM participant party to a CCA shall be a downstream participant subject to the standard provisions for Innovation Center models specified in subpart A of this part 512.

As proposed, a CCA would be exclusively between an ASM participant and a primary care practice. We considered expanding this definition to allow multiple ASM participants in the same TIN to enter into a CCA with a primary care practice. We were concerned about the burden that may be introduced by having each ASM participant enter these arrangements individually; however, elevating the arrangement to the TIN level opens risks of not being able to accurately track remuneration exchanged between the parties under a CCA. We welcomed comments on our proposed CCA definition and how to address the burden it may impose on ASM participants and partnered primary care practices. We also welcomed comments on the types of services and remuneration that ASM participants may contemplate in their CCAs to meet improvement activity specifications or advancing at least one of ASM's three clinical goals as proposed at § 512.771(b).

We welcomed comments on these proposals at § 512.771(a) and (b).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed ASM CCAs, noting that CCAs would encourage coordination between specialists and PCPs, and promote outcomes while lowering costs for patients with chronic conditions. Similarly, another commenter supported the proposals on CCAs, because they would advance the goals of the ASM, foster better collaboration between specialists and primary care physicians, and improve quality of care and patient satisfaction.

Response: We appreciate the commenters for their support.

Comment: Several commenters expressed concern about the proposed CCA requirements in ASM, especially given the independent nature of many specialists and the variability in patient care settings. The commenters expressed concerns that patients often see primary clinicians not associated with specialists' practice or may not have a designated PCP.

Response: We appreciate the commenters for their feedback. However, ASM was designed to bridge the often independent nature of many specialists with PCPs. As such, the ASM improvement activities performance category is precisely intended to establish care coordination pathways between specialists and PCPs who would not otherwise have the incentive to formalize their communications. Moreover, proposed IA-1 requires specialists to take a more active role in confirming that the ASM beneficiary has a PCP, or if they do not have one, assist the ASM beneficiary in finding a clinician who provides primary care services. Not only does this allow specialists to ensure their ASM beneficiaries are receiving necessary follow-up care to prevent exacerbation of their condition, but it also facilitates greater opportunities for cross-specialty innovation to benefit Medicare beneficiaries.

Comment: The commenters recommended that CMS allow flexible, system-level CCA implementation, provide standardized templates and guidance, and offer technical assistance and funding to support integration. Another commenter recommended that CMS publish a model CCA template outlining minimum elements, such as information-sharing, care-transition expectations, and escalation pathways and allow secure e-signatures to streamline coordination.

Response: We appreciate the commenters for their feedback. At this time, we do not intend to provide funding to support the integration of CCAs into specialist and PCP workstreams. We intend to provide resources and materials to support the improvement activities performance category requirements, such as CCAs. We intend to make these resources available on the model website. However, we note that would prefer to allow ASM participants and any collaborative care partners to negotiate arrangements that are best suited to their practices. As we continue developing operational processes around CCAs, we will release additional guidance, if applicable.

Comment: A few commenters recommended that CMS clarify when CCAs are required between PCPs and specialists. A commenter also recommended CMS to exclude CCA requirements for ASM participants in Shared Savings Program or REACH ACOs to reduce redundancy and burden. The

commenters also recommended CMS provide bonus points to independent or small-practice specialists participating in CCAs with PCPs in an Advanced APM.

Response: To receive the maximum score available for the ASM improvement activities performance category, ASM participants must enter into at least one CCA with a clinician who provides primary care services to at least one shared ASM beneficiary. Regarding the commenter's suggestion to exclude ASM participants in the Shared Savings Program or ACO REACH from CCA requirements, we do not believe the establishment of a CCA requirement is redundant since ASM's CCA requirements have meaningful deviations from primary care relationship requirements in ACO REACH or the Shared Savings Program. Rather, ASM participants who are already in the Shared Savings Program and ACO REACH should be able to leverage existing care collaboration relationships to fulfill ASM's CCA requirement. We appreciate the suggestion of providing bonus points to small practice specialists that form CCAs with PCPs in an Advanced APM. We note that we will provide eligible ASM participants a positive small practice scoring adjustment on their final score; however, that scoring adjustment is not tied specifically to ASM participants in small practices that are also participating in an Advanced APM. We do not believe that limiting that adjustment to Advanced APM participants would be appropriate because the goal of the small practice scoring adjustment is to provide a fair adjustment for all ASM participants in small practices.

Comment: A few commenters expressed concern that the proposed CCAs may not advance ASM goals and could create conflicting incentives between PCPs and specialists, potentially leading to misalignment, tension, and greater fee-for-service uptake. The commenters also shared their concerns about a lack of clear incentives and support for transitioning to shared accountability and aligned financial models.

Response: We appreciate the commenters for their feedback and agree that additional support for transitioning to shared accountability and aligned financial models is necessary. We particularly agree that clear incentives are necessary to ensure all parties to a CCA are equally accountable for the health outcomes of their shared ASM beneficiaries. Thus, we are refining our proposal at § 512.771(a)(7) to clarify that payments between the parties to a CCA cannot exceed the sum total of the payment adjustments made to an ASM participant's claims for a given ASM payment year as a result of the

application of the ASM payment adjustment factor to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year. For example, if an ASM participant earns an ASM payment adjustment factor of +4 percent for the 2029 ASM payment year, then that ASM participant cannot offer remuneration to a CCA partner that is greater than the sum total of the difference between the amount they receive in Part B payments for CY 2029 minus the amount they would have received for applicable Part B payments for CY 2029 without the ASM payment adjustment factor. Similarly, if the ASM participant receives an ASM payment adjustment factor of -4 percent, then the ASM participant cannot recover from their CCA partners more than greater than the sum total of the difference between the amount they receive in Part B payments for CY 2029 minus the amount they would have received for applicable Part B payments for CY 2029 without the ASM payment adjustment factor. We believe this is a fair and reasonable refinement of our proposed policy as it ties potential financial incentives associated with CCAs with patient outcomes, similar to the distribution of shared savings and losses in ACO models, and thus is sufficiently related to ASM's clinical goal identified at § 512.771(b)(3) to "increase independent physician participation in value-based payment programs." We did not propose a definition for "value-based payment programs" because it is an industry-acknowledged term that rewards program participants for making improvements in accepted and evidence-based quality standards and processes.[302] Thus, the modifications serve to clarify how we intend ASM participants to structure any CCAs that involve financial components.

This refinement also ensures that ASM participants who introduce a financial component to their CCAs continue to comply with all applicable statutes, regulations, and guidance, as stated in proposed § 512.771(a)(5).Per OIG's rationale for the creation of the CMS-sponsored model safe harbors at § 1001.952(ii) at 84 FR 55694 the significant flexibility of the safe harbor relied upon the Innovation Center's ability to oversee, monitor, and embed program integrity protections in the models. To ensure ASM upholds the standards for program integrity contemplated by the OIG in making this safe harbor available for ASM participants, we are also identifying a requirement for all ASM participants to screen any potential care collaborators against the OIG Exclusion List. The OIG Exclusion List is a publicly

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[302] Kim H, Mahmood A, Hammarlund NE, Chang CF. Hospital value-based payment programs and disparity in the United States: A review of current evidence and future perspectives. Front Public Health. 2022 Oct 10;10:882715. doi: 10.3389/fpubh.2022.882715. PMID: 36299751; PMCID: PMC9589294.

available, searchable website that identifies individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal health care programs. We considered requiring ASM participants to regularly submit lists of all non-ASM participant parties with which they have established CCAs but recognized the high level of administrative burden on both the ASM participant and on CMS resources. Thus, while we will not require ASM participants to submit information on the primary care practitioners with whom they have executed CCAs on a regular basis, we reserve the right at § 512.150 to request such a list as part of CMS monitoring and compliance activities at any time in a form and manner to be determined by CMS.

Regarding commenters' concerns about conflicting incentives created by CCAs between participants and primary care practitioners, we do not agree with the commenters' statement that CCAs may create tension and shift care patterns in an undesirable direction. Using lessons learned from Making Care Primary (MCP) and ACO REACH, ASM's CCA requirements focus on improving communication and information-sharing between specialists and primary care practitioners. They are not intended to reward more visits, and instead, are meant to reduce the volume of medically unnecessary or duplicative care by encouraging shared responsibility for the ASM beneficiary's health outcomes between ASM participants and primary care practitioners.

After consideration of public comments, we are finalizing our proposals with modifications to support the transition to shared accountability between ASM participants and their collaborative care partners and to ensure ASM participants perform their due diligence in ensuring their care collaborators are not excluded from participation in Federal health programs.

(3) Application of the CMS-Sponsored Model Arrangements and Patient Incentives Safe Harbor to ASM Beneficiary Incentives and Collaborative Care Arrangements (CCAs)

Consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. As noted in the CY 2026 PFS proposed rule, no fraud or abuse waivers are being issued in this final rule; fraud and abuse waivers, if any, would be set forth in separately issued documentation (90 FR 32624). Any such waiver, if issued, would apply solely to ASM and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this final rule, ASM

participants must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued under section 1115A(d)(1) of the Act specifically for ASM.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS proposed to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2)) is available to protect remuneration exchanged under certain CCAs and patient incentives that may be permitted under the final rule, if issued. Specifically, we proposed at §§ 512.765(a) and (b) that the CMS-sponsored models safe harbor would be available to protect CCAs and ASM beneficiary incentives so long as they meet specified requirements at proposed §§ 512.770 and 512.771 under the model and the requirements of the safe harbor at § 1001.952(ii).

We considered not allowing use of the respective safe harbor provisions for ASM participants who enter into CCAs or who wish to provide beneficiary incentives. However, we determined that use of the safe harbor would encourage the goals of the model. We believe that a successful model requires integration and coordination among ASM participants and other health care providers and suppliers. We believe the use of the respective safe harbor provisions available for CCAs and beneficiary incentives would encourage and improve beneficiary experience of care and coordination of care among providers and suppliers. We also believe these safe harbor provisions offer flexibility for innovation and customization of the patient care experience. Use of the respective safe harbor provisions for CCAs and beneficiary incentives allow for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

Thus, we proposed at § 512.765 making the CMS-sponsored model arrangements and patient incentives safe harbor at §§ 1001.952(ii)(1) and 1001.952(ii)(2) available for ASM participants to foster stronger connections with PCPs in their communities and to promote a more holistic approach to ASM beneficiary care outcomes, so long as they comply with the requirements of the safe harbor at § 1001.952(ii) and with the proposed requirements at §§ 512.770 and 512.771. We sought public comments on this proposal.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed at § 512.765.

l. Evaluation Approach

(1) Background

ASM is designed to incentivize specialist providers to engage in accountable care and aims to improve quality of care while lowering spending. An evaluation of ASM would be required in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center (84 FR 34533). All Innovation Center models are rigorously evaluated on their ability to improve quality of care and reduce costs. Additionally, we routinely monitor Innovation Center models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. Outlined later in this section are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed ASM.

(2) Design and Evaluation Methods

We proposed an evaluation methodology for ASM that would be consistent with the standard Innovation Center evaluation approaches that we have taken in other models, such as TEAM and CJR. Specifically, the evaluation design and methodology for ASM would be designed to allow for a comparison of historic patterns of care among ASM participants to any changes made in these patterns in response to ASM. The overall design would include a comparison of ASM participants with comparable specialist providers not participating in ASM to help us discern simultaneous and competing providers and market level forces that could influence our findings.

Our proposed evaluation methodology for this model builds upon our proposal to use CBSAs and metropolitan divisions as the geographic unit of selection for participation in the model based on a stratified random assignment as described in section III.C.2.c.(4) of this final rule. Under this approach, researchers evaluate the effects of the model on outcomes of interest by directly comparing CBSAs and metropolitan divisions that are randomly selected to participate in the model to a comparison group of CBSAs and metropolitan divisions that were not randomly selected for the model but could have been. Randomized evaluation designs of this kind are widely considered the “gold standard” for social science and medical research because they ensure that the systematic differences are reduced between units that

do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. With these methods, we would be able to examine the experience of the ASM participants over time relative to those in the comparison group controlling for as many of the relevant confounding factors as is possible. The evaluation would also include rigorous qualitative analyses to understand the contextual factors influencing the implementation and impact of ASM and the evolving nature of care delivery transformation.

In our proposed evaluation methodology, we plan to account for the impact of ASM at the geographic unit level, the TIN/NPI level, and the beneficiary level. We would also consider various statistical methods to address factors that could confound or bias our results. We would also account for clustering of beneficiaries within TINs and markets. Accounting for clustering ensures that we do not overstate our effective sample size by failing to account for the fact that the performance of participants in a market may not be fully independent of one another. Accounting for clustering may also improve statistical precision and allow us to better examine how patterns of performance vary across TINs and markets. Thus, in our analysis, if a large TIN consistently has poor performance, clustering would allow us to detect improved performance in the other, smaller TINs in a market rather than place too much weight on the results of one TIN and potentially lead to biased estimates and mistaken inferences.

Finally, we plan to use various statistical techniques to examine the effects of the ASM while also accounting for the effects of other ongoing interventions such as the Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding ASM in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

(3) Data Collection Methods

As part of our proposed evaluation methodology, we proposed to consider multiple sources of data to evaluate the effects of ASM. We expect to base much of our quantitative analyses on secondary

data sources including Medicare FFS claims. The beneficiary claims data would provide information such as utilization and expenditures in total and by type of provider and service. In conjunction with the secondary data sources mentioned previously, we would consider a CMS-administered survey, guided interviews, and focus groups of beneficiaries who experienced a heart failure or low back pain episode during the ASM test period. This survey would be administered to ASM beneficiaries who were in an episode or similar patients selected as part of a control group. The primary focus of this survey would be to obtain information on the ASM beneficiary's experience in episodes relative to usual care. We are also considering a survey administered by CMS to ASM participants. These surveys would provide insight into providers' experience under the model and further information on the care redesign strategies undertaken by health care providers.

In addition, we would consider site visits and focus groups with selected active ASM participants. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring between ASM participants and other providers. For example, these data would help us better understand ASM participants' plans for engagement with PCPs in accountable care arrangements, as well as how those plans were implemented and what they achieved. Additionally, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to capture variations in implementation as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

We are considering the primary data collection efforts with providers and beneficiaries within the comparison group. The systematic data collection from comparison group providers would allow for parsing out changes in standard of care from the ASM impact. Additionally, primary data collection with beneficiaries who received care at comparison group providers would provide critical information about the impact of the model on self-reported health status, experience of care and overall satisfaction.

(4) Key Evaluation Research Questions

Our evaluation would assess the impact of ASM on the dual aims of improved care quality and reduced costs. The evaluation would include assessments of Medicare expenditures, utilization, quality

outcomes, and patient experience of care. Our key evaluation questions would include, but are not limited to, the following:

- Payment. Is there a reduction in Medicare expenditures in absolute terms? By subcategories including major cost drivers for heart failure and low back pain episodes? Does ASM reduce variations in expenditures that are not attributable to differences in health status? Did ASM result in net savings to the Medicare program, after accounting for any payment adjustments made under the model?
- Utilization. Are there changes in Medicare utilization patterns overall and for specific types of services including services identified as "low value"? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes, and general clinical judgment of appropriate care?
- Quality of care. What impact did the model have on quality of care for beneficiaries? Did the incidence of relevant clinical outcomes such as hospital admissions remain constant or decrease? Were there changes in beneficiary outcomes under the model compared to appropriate comparison groups?
- Beneficiary experience. What impact did the model have on beneficiary experience overall and for beneficiary subgroups? Did the model have an impact on beneficiaries' engagement in their health care decisions?
- Care delivery transformation. How has provider behavior in the mandatory geographic areas changed under the model? Is there evidence of broader market-level changes? Are provider relationships changing over the course of the model? Is the model facilitating continuity of care between specialty and PCPs? Is there evidence that the participants' changes in care delivery that were made in the response to the model will be sustained?
- Unintended outcomes. Did ASM result in any unintended consequences, including adverse selection of patients, access problems, cost shifting, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? If so, how, to what extent, and for which beneficiaries or providers?

(5) Evaluation Period and Anticipated Reports

As discussed in section III.C.2.b. of this final rule, we proposed that the ASM test period would be 7 years that includes both ASM performance years and ASM payment years. The evaluation period

would encompass the ASM test period. We would plan to evaluate ASM on an annual basis. However, we recognize that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while we intend to conduct periodic summaries to offer useful insight during the model test, a final analysis after the end of the 7-year ASM test period would be important for ultimately synthesizing and validating results.

We sought public comments on our proposed design, evaluation, data collection methods, and research questions.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters made recommendations on the proposed evaluation methodology. A commenter recommended that the agency monitor the model's impact on care coordination, access, and clinician workload and that CMS should make midcourse adjustments as needed to protect patient care quality. Another commenter suggested that CMS assess whether care teams can successfully prevent major complications and ensure that services are coordinated around the primary episode. A commenter also recommended that CMS study successful integrated models, such as Allina Health integrated pain management programs; use existing data from integrated pain programs showing improved outcomes and reduced cost; and ensure access to comprehensive pain management options for all Medicare beneficiaries.

Response: We appreciate the commenters for their feedback on the ASM evaluation methodology. The evaluation approach will measure the model's impact on various measures of quality of care, including care coordination, care utilization, beneficiary experience, and provider experience with ASM. The evaluation will measure important outcomes such as the rate of adverse events and, to the extent possible, will collect primary data, including qualitative data, to understand the model's implementation and impact.

Comment: A commenter recommended that CMS evaluate ASM by comparing cost and quality measures between participating and non-participating physicians, and by assessing changes in physician performance over time, rather than requiring participation or limiting the model to randomly selected regions.

Response: We appreciate the commenter for their feedback on the evaluation approach. A mandatory, randomized selection approach allows for a more robust and reliable evaluation compared to voluntary participation because it allows us to account for unobserved differences between physicians and practices that may account for differences between the intervention and comparison groups. We believe that the current approach is preferable in order to allow for a reliable evaluation.

Comment: A few commenters offered recommendations regarding the proposed analytic methods to evaluate the ASM. The commenters recommended that CMS implement robust monitoring to ensure beneficiary access is not negatively affected by ASM and use quality measures to assess whether care teams are meeting patient goals.

Response: We appreciate the commenters for their feedback on the ASM evaluation methodology. The evaluation approach will measure the model's impact on various measures of quality of care, including beneficiary experience. The evaluation approach accounts for primary data collection, such as interviews and focus groups, to help measure beneficiary experience and aspects of care quality that cannot be captured from secondary data sources.

Comment: A few commenters supported the proposed ASM evaluation approach, noting that ASM would improve quality of care, reduce costs, incentivize specialists to prioritize outcomes and enhance greater collaboration and coordination of care between PCPs and specialists.

Response: We appreciate the commenters for their feedback on the proposed ASM evaluation approach. We agree that ASM is positioned to improve quality of care, reduce costs, and enhance collaboration and coordination of care between PCPs and specialists. The proposed evaluation approach is designed to accurately and robustly measure the impact of the model on these outcomes.

Comment: A few commenters offered additional recommendations for CMS to consider in ASM evaluation, such as evaluating reduced Part A spending based on improved utilization outcomes and capabilities of clinicians and practices to handle complexity of care. A commenter recommended that CMS prioritize model designs that align incentives to reward meaningful care transformation and equitably share savings, improving financial outcomes for both CMS and ASM participants.

Response: We appreciate the commenters for their feedback on the ASM evaluation methodology. The current evaluation approach will measure the impact of the model on total spending,

including Parts A and B, and will also measure impact on several utilization measures, including services such as imaging and surgeries, and adverse events such as hospitalizations and ED visits.

Comment: A few commenters requested additional information regarding the specific methodology and criteria CMS will use to determine whether a service administered under the model is of low value, and how patient complexities and comorbidities will be integrated into these assessments. A commenter additionally requested the clinical evidence to support the value determination.

Response: Studies in the literature have developed methods for identifying low-value service utilization low back pain services including for back imaging, spinal injections, and vertebroplasty or kyphoplasty using claims data. CMS plans to identify and measure low-value use of these services based on specific criteria (for example, diagnoses) developed from the literature. Two relevant studies include:

(1) Schwartz, A. L., Landon, B. E., Elshaug, A. G., Chernew, M. E., & McWilliams, J. M. (2014). Measuring low-value care in Medicare. JAMA internal medicine, 174(7), 1067–1076. https://doi.org/10.1001/jamainternmed.2014.1541.

(2) Fleming, C., Shin, E., Powell, R., Poznyak, D., Javadi, A., Burkhart, C., Ghosh, A., & Rich, E. C. (2022). Updating a Claims-Based Measure of Low-Value Services Applicable to Medicare Fee-for-Service Beneficiaries. Journal of general internal medicine, 37(13), 3453–3461. https://doi.org/10.1007/s11606-022-07654-7.

After consideration of public comments, we are finalizing our proposed design, evaluation, data collection methods, and research questions.

m. Overlap with Other Models Tested Under Section 1115A and CMS Programs

We proposed to permit ASM to overlap with other Innovation Center models and CMS programs, with the exception of MIPS, from which ASM participants would be excluded from reporting and participation, as proposed in in the CY 2026 PFS proposed rule (90 FR 32627).

We intentionally designed ASM to apply to Medicare FFS beneficiaries that are assigned, aligned, or attributed to other CMS Innovation Center models, such as existing or forthcoming population-based total cost of care models, or CMS programs, such as the Shared Savings Program, while ensuring compatibility and alignment towards improving care and reducing spending. The ASM payment methodology allows for overlaps between ASM and other Innovation Center models or CMS programs

by avoiding shared savings payments to participants in more than one shared savings model, as barred by statute in 42 USC 1395jjj(b)(4)(A).

Overlapping incentives are key to aligning incentives across the care team because clinicians are more likely to change their behavior or engage in care transformation when the incentives directly affect them.[303] Because specialists drive the majority of spending within Original Medicare, increasing specialist awareness of their participation in ACOs and better engaging them in care transformation is key.[304,305] Given this objective, ASM would apply to all clinicians meeting the ASM participant eligibility criteria, regardless of whether the clinician is excused from reporting to MIPS due to Advanced APM participation or if the clinician is exempt from reporting MIPS due to eligibility requirements. One reason that we proposed to include this broad selection of clinicians as part of ASM is to encourage more specialist engagement with ACOs. The benefits of driving further specialist engagement in value-based care outweigh the additional burdens, especially given the specialists' patient panels make up a smaller portion of ACO-assigned beneficiaries relative to primary care.[306]

Furthermore, for any clinician who achieves Qualifying APM Participant (QP) status in an Advanced APM, the QP is waived from reporting and participating in MIPS (81 FR 77062). In addition, participation in MIPS is optional for those Advanced APM participants who are partial QP (81 FR 77014). ASM, however, was designed to purposely overlap with Advanced APMs and ACOs to increase engagement of specialists, regardless of organizational structure. And for specialists participating in an ACO, ASM intends to capture Medicare FFS beneficiaries across the entire specialist practice rather than only the subset of beneficiaries assigned to the ACO. This would expand the impact of incentives beyond those beneficiaries assigned to the ACO to the specialist's full panel of beneficiaries who are treated for each relevant condition. This ensures that ACOs are enabled by a landscape of specialists, whether

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[303] Leao DLL, Cremers HP, van Veghel D, Pavlova M, Groot W. The Impact of Value-Based Payment Models for Networks of Care and Transmural Care: A Systematic Literature Review. Appl Health Econ Health Policy. 2023 May;21(3):441-466. doi: 10.1007/s40258-023-00790-z.

[304] Markovitz AA, Ryan AM, Peterson TA, Rozier MD, Ayanian JZ, Hollingsworth JM. ACO Awareness and Perceptions Among Specialists Versus Primary Care Physicians: a Survey of a Large Medicare Shared Savings Program. J Gen Intern Med. 2022 Feb;37(2):492-494.

[305] Lewis, Valerie A.; Schoenherr, Karen; Fraze, Taressa; Cunningham, Aleen. Clinical coordination in accountable care organizations: A qualitative study. Health Care Management Review 44(2):p 127-136, 4/6 2019.

[306] Barnett ML, McWilliams JM. Changes in specialty care use and leakage in Medicare accountable care organizations. Am J Manag Care. 2018 May 1;24(5):e141-e149.

participating in an ACO model or not, who are more likely to cooperate in care transformation to achieve their shared goals.

For these reasons, we proposed to allow overlaps between ASM and other Innovation Center models and CMS programs. We proposed that this model would apply to all clinicians meeting the eligibility criteria, regardless of whether the clinician is exempt from MIPS reporting during ASM's performance year due to QP status or Partial QP status as a result of meeting the thresholds for payments or patients tied to participation in an Advanced APM. We sought comment on the proposal to permit overlap between ASM and other Innovation Center and CMS programs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters generally supported the proposed approach to include all clinicians participating in other Innovation Center models that meet the proposed participant eligibility criteria in ASM. Another commenter supported CMS' efforts to enhance ACO-specialist risk arrangements with specialists in total cost of care models. Many commenters recommended that CMS exclude Advanced APMs and clinicians that have QP status or Partial QP status from another model from ASM or allow them to voluntarily opt-in to ASM. The commenters expressed their concerns that applying ASM requirements to QPs undermines MACRA's intent, imposes unnecessary burdens, and risks discouraging participation in APMs, particularly among specialists

Response: We appreciate commenters for their feedback supporting ASM overlap with other Innovation Center models. We also acknowledge their concerns that clinicians with QP or Partial QP status under the Quality Payment Program should be excluded from ASM or allowed to voluntarily participate As we wrote in the CY 2026 PFS proposed rule, we designed ASM so that it would capture a greater share of FFS beneficiaries with ASM's targeted chronic conditions, creating opportunities to improve quality and reduce unnecessary and low-value care spending related to these conditions (90 FR 32627). For ASM participants participating in ACO models, only a subset of their FFS beneficiaries with ASM's targeted chronic conditions may be attributed to the ACO, meaning that a portion of these beneficiaries receiving services from the ASM participant are potentially not within an accountable care arrangement. We believe that allowing for overlap would increase the number of FFS

beneficiaries whose specialists are being held accountable for care furnished related to ASM's targeted chronic conditions. We also believe that the layering of incentives between ASM and other models or initiatives creates a complementary but direct incentive on specialists, including those associated with an ACO, to improve care and reduce unnecessary spending. For these reasons, we believe that mandatory participation regardless of QP, Partial QP status, or participation in another APM is appropriate to achieve ASM's goals. Regarding the suggestion for a voluntary opt-in, we did not propose or consider a voluntary opt-in for certain types of ASM participants in the CY 2026 PFS proposed rule, so we believe these comments are out of scope.

We disagree that ASM would discourage specialist participation in other APMs. Given ASM's model overlap policy, we would not preclude an ASM participant from participating in another model or receiving other models' incentives, such as the Advanced APM conversion factor, should they qualify. We also disagree that ASM undermines MACRA's intent. While ASM leverages the MIPS performance assessment framework, ASM is a separate Innovation Center model that waives MIPS requirements. While we did not propose that ASM would meet the criteria for Advanced APM status in the CY 2026 PFS proposed rule, we will consider if there are ways for ASM to qualify as an Advanced APM in the future based on the Advanced APM requirements.

We acknowledge that ASM would have some level of burden for ASM participants to meet its requirements. We believe that we have introduced features into the model to mitigate this burden, such as allowing for group-level reporting of certain ASM performance categories. We also believe that the burden associated with participation in ASM is required to achieve increased accountability on specialists managing beneficiaries with ASM's targeted chronic conditions.

Comment: A few commenters voiced concerns that ASM is not an Advanced APM and does not offer a pathway to specialty-focused Advanced APM participation. The commenters shared their belief that ASM would increase financial risk and administrative burden to specialists without providing the benefits of qualifying APM participant status, hindering CMS' goals of advancing value-based care. The commenters further recommended that CMS develop approaches to create a pathway into Advanced APM participation and collaborate with specialists to design models that enable clinicians to qualify as for QPs.

Response: We appreciate the commenters' questions and feedback about whether ASM would qualify as an Advanced APM. We will consider if there are ways for ASM to qualify as an Advanced APM in the future based on the Advanced APM requirements as defined at § 414.1415.

Comment: Many commenters were concerned about the proposed ASM overlap with the Shared Savings Program, noting concerns that allowing overlapping participation in both models could create conflicting incentives, duplicative penalties, increased administrative burdens, and fragmentation of care. A commenter shared their belief that specialists are motivated to participate in ACOs, in part, to avoid MIPS reporting requirements. Several commenters further recommended that ASM implement approaches to reduce redundancy, streamline compliance, and reduce conflicting obligations for clinicians participating in both programs.

Response: We appreciate the commenters for their feedback on our proposals to allow overlap between ASM and the Shared Savings Program. As we discussed in the CY 2026 PFS proposed rule, we designed ASM to increase engagement of specialists, regardless of organizational structure (90 FR 32627). For ASM participants that participate in the Shared Savings Program, ASM intends to capture more Medicare FFS beneficiaries across the entire specialist practice rather than only focusing on accountable care relationships with beneficiaries assigned to a Shared Savings Program ACO. We do not believe that dual participation in ASM and the Shared Savings Program would lead to fragmentation of care as we believe that care delivery approaches used by ASM participants in a Shared Savings Program ACO would help ASM participants perform well in ASM. Furthermore, we do not believe that overlap would create conflicting or duplicative penalties. ASM's payment incentives are targeted towards Part B payments for covered professional services and would not conflict with any potential shared savings an ASM participant could earn through Shared Savings Program participation. We acknowledge that ASM would require the reporting of some measures and attestations that are different from Shared Savings Program's requirements, and would, therefore, introduce some level of burden. However, we believe that the reporting requirements, which are distinct from MIPS requirements, are necessary to expand specialist accountability for a larger number of FFS beneficiaries to improve quality and reduce unnecessary spending related to ASM's targeted chronic conditions.

Comment: A few commenters expressed concerns about the potential overlap of the ASM with

existing Innovation Centers models, citing increased provider burden, operational complexity, and duplication of efforts. A few commenters noted their concerns that participation in multiple models with differing quality and financial incentives could overwhelm clinicians, increase compliance costs, and reduce the effectiveness of each model, and recommended making ASM participation voluntary to reduce complexity. A few commenters raised potential concerns about the suitability of specialists as care coordinators for chronic conditions when patients are already aligned with PCPs through accountable care arrangements and recommended that specialists retain flexibility to collaborate with PCPs rather than operate under a parallel, mandatory accountability structure.

Response: We appreciate commenters for sharing their concerns related to the overlap of ASM with other Innovation Center models. We discussed in the CY 2026 PFS proposed rule (90 FR 32627) and in the preamble of this section of this final rule that intentionally allowing for overlap with other Innovation Center models would increase direct incentives on specialists, which would incentivize them to improve care for FFS beneficiaries with ASM's targeted chronic conditions. When incentives directly affect a clinician, they are more likely to change their behavior or engaged in care transformation.[307] We disagree that adding non-conflicting incentives would overwhelm clinicians or reduce the effectiveness of each model; we believe that these layered incentives could increase the effectiveness of individual models in improving care and reducing unnecessary spending. We disagree that voluntary ASM participation would reduce complexity. As we have discussed in section III.C.2.c.(1) of this final rule, voluntary participation undermines the model test due to selection bias concerns and is the not preferred policy approach. We acknowledge that ASM participants would face a burden in meeting ASM's requirements; however, we believe that the reporting requirements are necessary to expand specialist accountability. We also acknowledge that both PCPs and specialists have a role in managing chronic conditions, like heart failure and low back pain. However, we believe that there is an opportunity to increase the incentives on specialists for improving chronic condition management for select conditions. As we discuss in section III.C.1. of this final rule, we designed ASM with a focus on specialists who commonly treat patients with

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[307] Leao DLL, Cremers HP, van Veghel D, Pavlova M, Groot W. The Impact of Value-Based Payment Models for Networks of Care and Transmural Care: A Systematic Literature Review. Appl Health Econ Health Policy. 2023 May;21(3):441-466. doi: 10.1007/s40258-023-00790-z.

certain chronic conditions in the ambulatory setting, develop longitudinal relationships with patients, and co-manage beneficiaries with PCPs. Specialists who treat chronic conditions are likely to benefit from improved integration between specialty and primary care to maximize opportunities for high-value care. Therefore, we do not view these accountability structures to run in opposition or in parallel; rather, the accountability structures on both PCPs and specialists would function synergistically to improve chronic condition management.

Comment: Several commenters recommended that CMS provide additional clarification on the payment reconciliation methodology for ASM participants that participate in other models to account for financial overlap between models. The commenters specifically expressed concern regarding how CMS would reconcile the overlap in the attribution of clinicians to beneficiaries and how the overlap in redistribution payments would include shared savings. Several commenters suggested CMS to consider the potential interaction of ASM with total cost of care measures and the Shared Savings Program, and recommended that CMS exclude participants from ASM payment adjustments. A commenter recommended that CMS evaluate how substantially higher upward adjustments and payment distributions under ASM could potentially affect the financial methodologies used by ACOs.

Response: We appreciate commenters for raising their concerns on allowing model overlap and how ASM payment adjustments could influence payment reconciliation methodologies in other models, particularly ACO models. At this time, we intend for ASM payment adjustments to be handled the same way that MIPS payment adjustments are accounted for in ACO benchmarking calculations. We believe this treatment would be appropriate given the relatively similar risk level between ASM and MIPS, particularly in the first 2 payment years, and the similar application of the payment adjustments on Part B payments for covered professional services. We will continue to work with relevant teams across the Innovation Center and CMS to coordinate on these methodologies. Should we adjust the treatment of ASM payment adjustments in other models or programs' pricing or payment methodologies, we would do so through the appropriate regulatory channel or through additional guidance issued by the applicable model or program.

Comment: A commenter supported the proposal to allow for ASM overlap with other Innovation Center models and programs but did not support overlap with MIPS.

Response: We appreciate the commenter's support for allowing ASM to overlap with other Innovation Center models. However, we note that ASM would not overlap with MIPS. As discussed in section III.C.2.h.(2) of this final rule, we will waive all ASM participants from participation in MIPS for any ASM performance year in which they meet the ASM participant eligibility criteria, unless otherwise specified at § 512.710(a)(2).

Comment: Several commenters requested clarification on how ASM would interact with other CMS programs and guidance on how participation, attribution, quality measures, and incentive payments will be handled for clinicians involved in multiple programs. Several commenters provided several recommendations to improve the integration of ASM with other CMS programs, with an emphasis on reducing administrative burden, eliminating requirements to submit measures without an eCQM collection type, aligning incentives, and supporting value-based care through pathways for specialists transitioning into ACOs or Advanced APMs.

Response: We appreciate commenters for requesting further clarification on how ASM would interact with other CMS programs. We provide clarification throughout this section of this final rule on feedback we received about model and program-specific interactions and overlaps. As we described in the CY 2026 PFS proposed rule (90 FR 32627) and in this final rule, our current position is that ASM participants will not be excluded from participation in other Innovation Center models or CMS programs other than MIPS. We refer readers to section III.C.D.h.(2) of this final rule for further comments and responses related to the finalized MIPS waiver under ASM. Based on our finalized definition of ASM beneficiary at §512.705, we do not anticipate that beneficiary attribution in other Innovation Center models or programs would be affected by virtue of being identified as an ASM beneficiary. Regarding quality measures, our required quality measure set for each ASM cohort largely pulls from existing measures from other programs, primarily MIPS. We note that we have also tried to include several quality measures with an eCQM collection type and administrative claims-based measures to reduce provider burden. We refer readers to section III.C.2.d.(2) of this final rule for further discussion on how we aligned quality measures we other CMS programs. Regarding aligning payment incentives, as ASM would allow seamless overlaps with other models and programs (with the exception of MIPS), ASM participants would receive payment adjustments in ASM but remain eligible to receive other incentives from

participation in other models or programs. We refer readers to responses to comments throughout this section of this final rule on the rationale for allowing overlapping financial incentives under ASM and other models. Finally, we acknowledge commenters' recommendations to consider on-ramps for participants that may be transitioning into ASM from ACOs or other Advanced APMs. While we understand that preparing for participation in ASM would require time, we believe that ASM participants who previously participated in ACOs or other Advanced APMs would likely have much of the necessary infrastructure and workflows in place in order to meet ASM's requirements. We also note that the advanced notification of mandatory participation coupled with educational resources that we plan to provide ASM participants in advance of the model start date would support this group of ASM participants to prepare for the model.

Comment: A few commenters recommended that CMS ensure greater ACO incentives for clinicians participating in both models. Another commenter recommended that CMS consider implementing a pilot program as an alternative to ASM, offering ACOs with significant numbers of heart failure patients to improve beneficiary outcomes.

Response: We appreciate commenters for their ideas related to ACO-level incentives for ACOs that have participants in ASM. Our goal with ASM is to focus on increasing the incentives on specialists to improve outcomes and reduce unnecessary spending. Through engagement with specialists, ACOs and ASM participants have the opportunity to work collaboratively to improve beneficiary outcomes such as those related to heart failure or low back pain, and to potentially receive shared savings in part because of such efforts. We believe that ASM creates a stronger incentive on the specialist to improve upstream chronic condition management. For those ASM specialists associated with ACOs, there is then an even stronger incentive to improve the outcomes of beneficiary aligned to the ACO given the potential for shared savings. Any consideration of additional ACO incentives for clinicians participating in both ASM and an ACO would need to be taken up by the individual ACO model or applicable program.

Comment: A few commenters recommended potentially using a nested approach within broader population-health reforms like ACOs or prioritizing the total cost of care models over episodic care models. A commenter recommended that CMS develop approaches for engaging ACOs in bundled payments with specialists. A commenter recommended data transparency through "shadow bundle data"

reports to include all-payer data, enabling ACOs to better assess specialist performance and make informed partnership decisions.

Response: We appreciate the commenters' ideas on exploring a nested bundle approaches within total cost of care models, approaches for engaging ACOs in bundled payments with specialists, and all-payer shadow bundle data. These suggestions currently fall outside of the scope of provisions considered by ASM.

Comment: Commenters raised concerns about the potential burden, duplicative and resource-intensive efforts, and confusion for participants involved in the overlap between the ASM, the Transforming Episode Accountability Model (TEAM), and the Wasteful and Inappropriate Service Reduction (WISeR) models, highlighting that the overlap may create challenges for model implementation, evaluation, and attribution of quality and cost reduction outcomes for clinicians required to participate in all the three models.

Response: We appreciate commenters raising concerns about the potential burden, confusion, and attribution of quality and cost outcomes in evaluations that could result in ASM participants overlapping with TEAM and the WISeR model. We disagree with these concerns as we believe the potential overlap across the three models would support the delivery of clinically appropriate, evidence-based care that can lead to improved outcomes and reductions in unnecessary spending related to ASM's targeted chronic conditions.

TEAM is a 5-year mandatory alternative payment model tested by the Innovation Center that will begin on January 1, 2026, and end on December 31, 2030. TEAM will test whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories (90 FR 37074). TEAM requires eligible acute care hospitals within selected CBSAs to participate (89 FR 69663 through 69710). Further, TEAM will test five surgical episode categories: Coronary Artery Bypass Graft Surgery (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel Procedure, Surgical Hip/Femur Fracture Treatment (SHFFT), and Spinal Fusion (90 FR 37073). Based on the selected episodes in TEAM, we believe there could be synergistic effects across the models should a CBSA be selected for participation in both ASM and

TEAM. Given the different participant profiles and model requirements given TEAM's participants are hospitals whereas ASM's are individual clinicians practicing in an ambulatory setting, we do not believe that there is justification for excluding CBSAs selected for TEAM from selection in ASM. In fact, better care and efficiencies generated in TEAM during the post-discharge period after a surgery, such as a spinal fusion or CABG, could support better longitudinal condition management in ASM; the EBCMs on which we will score ASM participants include accountability for downstream care, such as inpatient services related to TEAM episodes.

The WISeR voluntary model targets select services that may be low-value or vulnerable to fraud, waste, and abuse. WISeR will test the use of enhanced technology to decrease certain wasteful (low-value) services shown to have little to no clinical, evidence-based benefit in six states.[308] To help reduce burden, WISeR is testing enhanced technology to help streamline prior authorization; prior authorization is also voluntary, and providers can opt to undergo pre-payment review after a claim is submitted. Further, WISeR does not change Medicare coverage or payment criteria; it simply enforces existing criteria as specified in the National or Local Coverage Determinations. WISeR includes services that may be applicable to ASM beneficiaries with low back pain such as vertebroplasty/kyphoplasty and epidural spinal injections. Helping to ensure these services are delivered appropriately can help ASM participants achieve their quality and cost goals. Similar to TEAM, we believe that potential synergies between ASM and WISeR could ultimately benefit beneficiaries.

We would also appropriately account for potential spillover effects from other models operating within ASM mandatory geographic areas should we believe it necessary and appropriate to do so. We refer readers to section III.C.2.l of this final rule for further discussion on ASM's evaluation approach.

After consideration of public comments, we are finalizing our proposal to permit ASM to overlap with other Innovation Center models and CMS programs, with the exception of MIPS, as proposed.

n. Application of Standard Provisions for Mandatory Innovation Center Models

ASM meets the criteria for application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A). We stated in the CY 2026 PFS proposed rule (90 FR 32627

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[308] https://www.cms.gov/priorities/innovation/innovation-models/wiser.

that unless otherwise specified, all ASM participants and ASM beneficiaries would be subject to the provisions at §§ 512.100 through 512.190, which address the following areas:

- Beneficiary Protections
- Cooperation in Model Evaluation and Monitoring
- Audits and Record Retention
- Rights in Data and Intellectual Property
- Monitoring and Compliance
- Remedial Action
- Innovation Center Model Termination by CMS
- Limitations on Review
- Miscellaneous Provisions on Bankruptcy and Other Notifications
- Reconsideration Review Process

We recognize the standard provisions were not intended to encompass all the terms and conditions that would apply to each Innovation Center model, because each model embodies unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that would continue to be included in each model's governing documentation. Thus, we sought public comment on whether ASM should set forth model-specific provisions related to any of the provisions identified earlier.

We did not receive public comments on the application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A) to ASM, and therefore, we are finalizing as proposed.

D. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS') Medicare Diabetes Prevention Program Expanded Model (hereafter, "MDPP" or "MDPP expanded model") is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012-2016).[309] The DPP model test successfully met statutory criteria for model expansion,[310] demonstrating 5 percent weight loss from their starting weight by participants (a key metric of the program's success) along with statistically significant reductions in Medicare spending, emergency department (ED) visits, and inpatient stays.[311] The MDPP expanded model was implemented through the rulemaking process in two phases, in the CY 2017 PFS (81 FR 80459 through 80483) and CY 2018 PFS final rules (82 FR 53234 through 53339).

MDPP was established in 2017 as an "additional preventive service,"[312] covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model tested by The CMS Innovation Center), CMS created a new MDPP supplier type through rulemaking in the CY 2017 PFS final rule (81 FR 80471), in addition to requiring organizations that wish to participate in MDPP to enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 intensive sessions furnished over 12 months, which consists of 16 core sessions delivered weekly over 6 months followed by core maintenance sessions delivered monthly in the following 6 months. MDPP sessions are delivered by a trained Coach who provides training on topics that include long-term dietary change, increased

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[309] The Health Care Innovation Awards funds awards to organizations that implemented the most compelling new ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid and Children's Health Insurance Program (CHIP), particularly those with the highest health care needs. The CMS Innovation Center announced the first batch of awardees for the Health Care Innovation Awards on May 8, 2012, and the second (final) batch on June 15, 2012. For more, see *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards*.

[310] Paul Spitalnic. Certification of Medicare Diabetes Prevention Program. Mar. 14, 2016. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf*.

[311] Rojas Smith. L., Amico, P., Hoerger, T. J., Jacobs, S., Payne. J., & Renaud, J.: Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report Addendum — August 2017 *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf* (pp. 858-914).

[312] 42 CFR 410.64 - *Additional preventive services*.

physical activity, and behavior change strategies for weight control and diabetes risk reduction. All sessions must adhere to a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum[313] and must be 1 hour in length. The primary goal of the MDPP expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss from the first core session (81 FR 80465).

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP on April 1, 2018 (82 FR 53237). As of March 2025, there were 331 approved MDPP suppliers.[314] The most recent MDPP evaluation report reflected that between April 2018 and September 2024, approximately 9,015 beneficiaries have participated in MDPP. Of these, 4,396 were Medicare FFS beneficiaries and 4,650 were MA beneficiaries.[315] Through the Diabetes Prevention Recognition Program (DPRP), CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards,[316] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test,[317] the CDC's National DPP,[318] and DPRP Standards,[319] please refer to the CY 2017 (81 FR 80471) and CY 2018 PFS (82 FR 52976) final rules and related websites.

The Public Health Emergency (PHE) for COVID-19 prompted changes to allow live, virtual delivery via distance learning for MDPP, among other changes (85 FR 84830 through 84841). Changes to MDPP in the in the CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (88 FR 78818) included a simplified payment structure to allow for FFS payments for beneficiary attendance while retaining the performance-based payments for diabetes risk reduction (that is, weight loss). Beginning January 1, 2024, payments are made to an MDPP supplier

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[313] CDC National Diabetes Prevention Program PreventT2 Curriculum and Handouts https://www.cdc.gov/diabetes-prevention/php/lifestyle-change-resources/t2-curriculum.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/prevention/resources/curriculum.html
[314] Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Unpublished data.
[315] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/*2025*/mdpp*-finalevalrpt.
[316] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.
[317] Health Care Innovation Awards. *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards*.
[318] *https://www.cdc.gov/diabetes/prevention/index.html*.
[319] *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

if an MDPP beneficiary attends any core session in the first 6 months or core maintenance session in the second 6 months, allowing payment for up to 22 sessions in a 12-month timeframe. The CY 2024 PFS final rule also extended certain PHE flexibilities, including the option to deliver some or all MDPP sessions via distance learning and for beneficiaries to virtually self-report weight for MDPP distance learning sessions, until December 31, 2027 (88 FR 79241).

CDC released the 2024 DPRP Standards[320] to replace the 2021 DPRP Standards in June 2024. The CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (89 FR 97710) made conforming changes to align with the 2024 CDC DPRP Standards and further clarify regulatory language pertaining to program delivery and claim submission by adding new MDPP terms for "in-person with a distance learning component" and "combination with an online component." The CY 2025 PFS final rule also updated self-reporting weight requirements for an MDPP distance learning session by providing beneficiaries with a new option to self-report their weight using two photos for distance learning sessions. In addition, the CY 2025 PFS final rule added a HCPCS modifier for reporting a make-up session on the same day as a regularly scheduled MDPP session, and bridge payments were removed from MDPP's FFS payment structure.

While the CY 2024 and CY 2025 PFS final rules included changes to MDPP, which included enhancements that simplified payment structure and extended the ability for MDPP suppliers to deliver some or all MDPP sessions via distance learning, additional changes to MDPP through the CY 2026 PFS final rule is necessary to increase uptake of MDPP. Participation in MDPP has been low, with less than 1 percent of eligible beneficiaries participating in the program. While an estimated 9.3 million Medicare FFS beneficiaries are potentially eligible for the program (that is, have a prediabetes diagnosis but not a diabetes diagnosis in claims), fewer than 10,000 Medicare beneficiaries have participated in MDPP during the first 6 years of the program.[321] Increasing the uptake of MDPP among both suppliers and beneficiaries is necessary to increase the impact and success of the program.

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[320] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

[321] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.

We proposed several changes which are aimed towards increasing the uptake of this important prevention-focused program while empowering beneficiaries and promoting further alignment between MDPP and the CDC DPRP Standards. Specifically, we proposed changes to 42 CFR 410.79(b) to add definitions for the following terms: Live Coach interaction, Online delivery period, and Online session while modifying the definition of "Online." We also proposed changes to the expanded model by amending § 410.79(c)(1)(ii) and (e)(3)(iii)(C) to address operational questions and barriers related to weight collection requirements. In addition, we proposed to extend flexibilities allowed during the PHE for COVID-19 through December 31, 2029, by modifying the definition of extended flexibilities period in § 410.79(b). Finally, we proposed to test the inclusion of an asynchronous delivery modality by modifying § 410.79 by revising paragraph (b) adding paragraph (f) and amending § 424.205(c)(10), (f)(2)(i), and (f)(5), which would allow MDPP suppliers to deliver the Set of MDPP services Online through December 31, 2029, clarify that MDPP suppliers are not required to maintain in-person delivery capability through December 31, 2029, and introduce a new G-code and payment for Online sessions. These changes are expected to expand beneficiary access to MDPP, reduce barriers to participation, improve MDPP session attendance and retention, and promote safety.

1. Changes to § 410.79(b)

The 2024 CDC DPRP Standards include the following delivery modes with definitions: "In-person," "Distance learning (live)," "In-person with a distance learning component," "Online (non-live)," and "Combination with an online component."[322] These delivery modes also serve as organization codes for CDC DPRP recognition. As indicated in § 410.79(b), distance learning refers to a MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video conference from another location.

The CY 2024 PFS final rule introduced and defined "distance learning" for MDPP and provided a definition for "Online delivery" (88 FR 79243). The CY 2025 PFS final rule modified the definition for

[322] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

"Online delivery" at § 410.79(b), to align with the 2024 CDC DPRP Standards[323] by revising the term from "Online delivery" to "Online" to align with both the MDPP "Distance learning" term and CDC DPRP "Online (non-live)" term (89 FR 98045). We also finalized the definition for the MDPP "Online" delivery mode to provide that sessions that are delivered 100 percent through the internet via smartphone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (non-AI)) Coach teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for Online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. E-mails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant, whereby both parties engage in the interaction. Chat bots and AI forums do not count as live Coach interaction. This modified definition added the term "non-live" and further clarified that Chat bots and AI forums do not constitute live interaction.

We proposed to amend § 410.79(b) by adding definitions for Live Coach Interaction and Online session while modifying the definition for "Online" at § 410.79(b) to clarify the Online delivery modality and remove requirements in the "Online" definition that would be outlined at § 410.79(f). We also proposed adding the definition of "Online delivery period", which refers to the 4-year period (January 1, 2026 to December 31, 2029) to test the inclusion of the Online delivery modality, described at § 410.79(f), to apply. During this time, MDPP suppliers may deliver the Set of MDPP services Online.

The CY 2024 PFS final rule extended certain PHE flexibilities finalized in the CY 2021 PFS final rule, including the option to deliver some or all MDPP sessions via distance learning and for beneficiaries to virtually self-report weight for MDPP distance learning sessions, until December 31, 2027 (88 FR 79241). In the CY 2024 PFS final rule, we finalized that during the Extended flexibilities period, MDPP suppliers may provide virtual services as long as they are provided in a manner consistent with the CDC DPRP standards for distance learning. The extension of these flexibilities allowed beneficiaries to obtain the Set of MDPP services either in-person, through distance learning, or through a combination of in-

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[323] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

person and distance learning for a proposed period of 4 years. The extended flexibilities definition refers to § 410.79(e)(3)(iii) and (iv), and the extended flexibilities period described at § 410.79(b) refers to the 4-year period (January 1, 2024 to December 31, 2027) for the extended flexibilities to apply.

Prior to the PHE for COVID-19, MDPP suppliers delivered the program predominantly in-person. Delivery modes have shifted over time, with an increasing number of beneficiaries participating through the virtual delivery option. The most recent evaluation report indicates that from April 2018 through March 2024, 59 percent of MDPP beneficiaries predominantly attended the program in person, 7.5 percent of MDPP beneficiaries attended the program through a mix of in-person and virtual sessions, and 33.5 percent predominantly attended the program virtually.[324] Among beneficiaries who participate in MDPP via distance learning or in-person with a distance learning component (hybrid), most expressed their satisfaction by citing the flexibility the choices provided when faced with challenges such as inclement weather or travel restrictions that made in-person participation difficult.[325]

We also proposed to extend flexibilities allowed during the PHE for COVID-19 through December 31, 2029 by revising the dates included in the definition for "extended flexibilities period" at § 410.79(b). In addition, we proposed extending this flexibility to promote continued access to MDPP for beneficiaries. In particular, beneficiaries in geographic areas with a limited number of in-person MDPP suppliers or other areas (for example, rural) where travel to an in-person session may be challenging and may be further exacerbated under certain circumstances, for example, during inclement weather.

This proposed change would ensure that all delivery modalities for MDPP are available during the same period of time (that is, through December 31, 2029) creating greater alignment, reducing potential confusion amongst beneficiaries and suppliers, and streamlining the program. Additionally, the proposed change would provide MDPP suppliers with a variety of modes in which to deliver the program and facilitate consistency across delivery modalities adhering to this same timeframe.

We proposed to amend § 410.79(b) and sought comments on these proposals. The following is a summary of the comments received and our responses.

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[324] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.
[325] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.

Comment: Several commenters supported to CMS' proposal to amend § 410.79(b) to add definitions for "Live Coach interaction, Online session, and Online delivery period," while modifying the definition of "Online." A commenter requested enhanced specificity in the definition for "Online" by incorporating the term "asynchronous" into the definition to distinguish between distance learning and Online sessions to reduce billing confusion.

Commenters expressed broad support for extending the PHE flexibilities for COVID-19 through December 31, 2029 by revising the dates included in the definition for "extended flexibilities period" at § 410.79(b). Many commenters emphasized that these flexibilities, particularly the distance learning modality, have demonstrated significant value in maintaining program access while enhancing session attendance, retention, and completion rates among beneficiaries. Commenters highlighted that the extended timeline would ensure operational continuity for MDPP suppliers while maintaining effective and flexible service delivery options to beneficiaries. In the March 2025 Evaluation of the Medicare Diabetes Prevention Program, beneficiaries participating in MDPP through distance learning or in-person with a distance learning component reported high satisfaction with flexibilities associated with these modalities.[326]

Some commenters suggested that CMS remove the once-per-lifetime use of MDPP at § 410.79(f), while other commenters advocated for making MDPP a permanent Medicare benefit to provide long-term stability and encourage continued beneficiary and supplier participation.

Response: We appreciate the suggestion to incorporate "asynchronous" into the definition of "Online' to distinguish it from distance learning. However, we proposed this definition to align with the 2024 CDC DPRP Standards, ensuring consistency across Federal programs. The definition for Online includes the term "asynchronous" in its description and establishes a 4-year testing period from January 1, 2026, to December 31, 2029, during which MDPP suppliers may deliver the complete Set of MDPP services Online using asynchronous delivery methods. Additionally, CMS will continue providing billing guidance and technical assistance throughout the Online delivery period. In response to public comments, we are finalizing the proposal to extend flexibilities allowed during the PHE for COVID-19 through

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[326]RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. *https://www.cms.gov/priorities/innovation/data-and-reports/*2025/*mdpp*-finalevalrpt.

December 31, 2029 as described at § 410.79(b) under “extended flexibilities period”.

We appreciate the commenters’ support for making MDPP a permanent Medicare benefit. We continue to explore pathways to ensure sustainability of diabetes prevention services and will continue to monitor program outcomes and beneficiary engagement to evaluate the program's success in preventing diabetes and achieving weight loss among Medicare beneficiaries. Additionally, comments regarding the once-per-lifetime requirement for MDPP and requests to establish MDPP as a permanent benefit are out-of- scope for this rule. Currently, CMS allows an exception to the once per lifetime requirement for MDPP beneficiaries to restart their MDPP program if their services were interrupted by the PHE for COVID-19 (85 FR 19283). We will continue to monitor use of this flexibility to approximate the demand for beneficiaries to restart their program for other reasons. After consideration of public comments regarding the proposed changes to amend § 410.79(b), we are finalizing the proposal to add definitions for “live Coach interaction”, “Online session”, and “Online delivery period,” while modifying the definition of “Online”.

2. Changes to § 410.79(c)(1)(ii) and (e)(3)(iii)(C)

Our policies for obtaining weight measurements for baseline weight and performance-based weight loss achievement goals are described at § 410.79(c)(1)(ii), and for the MDPP expanded model emergency policy, summarized at § 410.79(e)(3)(iii). Currently, these policies permit weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be taken in person by an MDPP supplier during an MDPP session, or via digital technology during the Extended flexibilities period. Specifically, these policies permit an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) in-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations; (2) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (3) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary (89 FR 98046).

The CY 2025 PFS policies regarding beneficiary weight self-reported measurements and virtual weight collection (89 FR 98045) provided additional flexibilities for beneficiaries to self-report their weights by providing 1 or 2 date-stamped photo(s) or a video recording of the beneficiary's weight, with

the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo(s) or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit one photo, this photo must show the beneficiary's weight on the scale with the beneficiary visible in their home. If choosing to submit two photos, the first photo must show the beneficiary's weight on the digital scale, and the second photo must show the beneficiary visible in their home.

Overall, commenters on the proposed MDPP Extended flexibilities in the CY 2024 PFS and CY 2025 PFS rules were very supportive of CMS continuing to allow virtual weight collection (88 FR 79240 through 79256 and 89 FR 98046). However, CMS received several comments regarding barriers to virtual weight collection experienced by MDPP suppliers and beneficiaries. This problem has become even more relevant as suppliers continue to provide distance learning to help reach beneficiaries in rural and underserved areas, sometimes across state lines.

For example, several commenters reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. The current weight collection requirements discourage individuals with mobility concerns from participating in MDPP due to risk of injury while self-reporting weight from home. Beneficiaries with mobility concerns may need to obtain weight at a medical office using a special scale (for example, wheelchair scale). Currently, beneficiaries do not have the option to submit medical record data as proof of weight, contributing to participant burden. Additionally, we have received feedback from suppliers stating that the requirement that beneficiaries must self-report weight by providing date-stamped photo(s) or video which must show the beneficiary's weight on the digital scale and the visible in their home is restrictive.

We acknowledge in our responses to these comments that some MDPP beneficiaries may lack the technology or capacity to provide a date-stamped photograph to document their body weight measurements. We previously stated that in situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in person (88 FR 79249). However, this may not be a practical option for beneficiaries who have chosen distance learning based on not living within driving

distance from an MDPP supplier location, lack access to transportation, or are participating from a location outside of their home or an in-person delivery site.

Therefore, we proposed revising § 410.79(c)(1)(ii) to allow for weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record within 2 days of the completion of the MDPP session. Currently, beneficiaries must weigh in during their in-person MDPP session or self-report weight measurements on the date associated with the billable MDPP session. We anticipated that suppliers and beneficiaries would appreciate the additional flexibilities surrounding weight collection for MDPP as current requirements may limit the ability of a beneficiary to report their weight from locations outside of an in-person delivery site or their home and prevent beneficiaries from submitting weight measurements documented in a medical record. We expected these additional flexibilities to empower beneficiaries, improve MDPP beneficiary engagement, session attendance, retention, and program completion. We considered alternative timeframes ranging from 3 to 5 days for this proposed change. We believe a 2-day documentation window prevented significant overlap between session documentation periods, considering core sessions occur weekly. We believe a shorter timeframe would be overly restrictive for suppliers and beneficiaries. We solicited public comments on this proposed timeframe and welcomed feedback on whether the 2-day documentation window was appropriate, or if alternative timeframes would better serve MDPP suppliers and MDPP beneficiaries while maintaining program integrity.

Additionally, we proposed revising § 410.79(e)(3)(iii)(C) to allow beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site. Examples of a reasonable location outside of an in-person delivery site include, but are not limited to fitness centers, medical facilities, and temporary abodes (for example, travel accommodations or a family member's home). Currently, beneficiaries must submit photo(s) or video documenting their weight on a digital scale from their home, which limits their ability to submit required weight measurements when on vacation or away from their home. We continue to require the date-stamp on photo(s) to ensure program integrity in the virtual setting.

We proposed amending § 410.79(c)(1)(ii) and (e)(3)(iii)(C). We solicited comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of our proposal at § 410.79(c)(1)(ii),

where we proposed to allow for the submission of weight collected as part of a medical record, dated within 2 days of a scheduled MDPP session, to reduce burden, promote safety, and increase access. In addition, a commenter believes that the ability to "use weight data from clinical visits or other reliable sources within the 2-day window (would) also help MDPP suppliers improve data integrity and reduce administrative burden." Another commenter believes the proposed change would "increase flexibility and better align with CDC DPRP standards, with the goal of boosting beneficiary uptake."

However, a few commenters raised concerns about the 2-day window between the scheduled MDPP session and weight documented in a medical record. Concerns ranged from no proposed allowance for weekends and holidays to inherent difficulties for beneficiaries residing in health professional shortage areas (HPSAs), where access to medical care is more limited. The majority of those maintaining these concerns suggested that we consider a 5- to 7-day period for weight collection as part of the medical record.

Response: We reconsidered the originally proposed 2-day timeframe used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record, which commenters indicated was overly restrictive. In the proposed rule, we initially considered timeframes ranging from 3 to 5 days and determined that a 2-day window would prevent overlap between session documentation periods for weekly core sessions. We are not extending the timeframe to 7 calendar days because this would place the documentation requirement too far from the actual session date and too close to the next weekly session, resulting in overlap between session documentation periods. After consideration of public comments, we are finalizing the changes to the provision at § 410.79(c)(1)(ii) to allow for weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record with an updated timeframe of 5 calendar days, which provides sufficient flexibility while maintaining clear separation between sessions.

Comment: In § 410.79(e)(3)(iii)(C), CMS proposed to update weight collection requirements to allow beneficiaries to self-report weight for MDPP sessions from home or a reasonable location outside of an in-person delivery site. Commenters supported this proposal and stated the change would increase flexibility, align with CDC DPRP standards, and increase beneficiary participation. More specific

feedback indicated that this change would be especially helpful for participants who face barriers to timely in-person weigh-ins, especially "rural populations, participants who are traveling, individuals with mobility challenges, transportation issues or caregiving responsibilities." Particularly, the current weight collection requirements limit the ability of a beneficiary participating from reporting weight from other reasonable locations outside of an in-person delivery site or home, such as a medical office if a beneficiary is unable to self-report weight safely from home, or hotel if the beneficiary is on vacation but otherwise able to participate in MDPP sessions.

While support for the proposed update to weight collection requirements to allow beneficiaries to self-report weight for MDPP sessions from home or a reasonable location outside of an in-person delivery site was nearly universal, CMS also received concerns about beneficiary safety and administrative burden. A commenter noted safety risks due to poor balance, poor coordination and physical limitations which could make weight self-reporting burdensome for MDPP. Similarly, other commenters considered technical requirements such as a date-stamped photo to be impractical and burdensome. Commenters requested that we consider other options, such as allowing multiple photos as a substitute for a date-stamped photo or explicitly allowing for weight reporting through Bluetooth™ scales via secure transmission.

Commenters requested additional guidance on acceptable technical parameters for weight collection. For example, a commenter noted that metadata and time stamp requirements on photos and videos taken on smartphones could satisfy weight collection requirements. Other commenters believe that digital scales and Wi-Fi technology should serve as acceptable substitutes for current weight collection requirements. Some commenters supported expanding MDPP performance metrics to include A1C measurements to better align with clinical outcomes.

Response: We are finalizing the proposal at § 410.79(e)(3)(iii)(C) to update weight collection requirements to allow beneficiaries to self-report weight for MDPP sessions from home or a reasonable location outside of an in-person delivery site due to strong support from commenters as proposed.

In response to public comments about safety risks associated with beneficiary weight self-reporting, we take these concerns seriously and have carefully considered feedback to ensure program integrity, flexibility, and beneficiary safety. The CY 2025 PFS final rule maintained safeguards for self-

reported weight measurements while specifying that beneficiaries can choose from a variety of methods to self-report weight. Specifically, the CY 2025 PFS final rule clarified that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or the MDPP supplier receives one or two date-stamped photo(s) or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier (89 FR 98047). The proposed changes to allow for weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record, and to allow beneficiaries to self-report weight for MDPP sessions from home or a reasonable location outside of an in-person delivery site, are aimed toward providing additional flexibility for beneficiaries to obtain weight measurements safely. We maintain that these multiple documentation options provide flexibility, maintain program integrity, and address safety concerns raised by commenters.

Additionally, regarding the comments requesting that photo metadata be used for the required date-stamp for self-reporting weight for an MDPP session, MDPP requires a date-stamped photo to provide verifiable documentation that weight measurements were taken on the session date, ensuring accurate reporting and preventing fraudulent submissions. At this time, and due to the out-of-scope nature of these comments in relation to our proposals, we are not further defining what constitutes a date stamp for the purpose of MDPP videos and photos under this regulation. We rely on suppliers to ensure a reasonable and reliable indication of the date connected to a picture or video. A physical date on the photo or video would satisfy this requirement. Similarly, we require photo documentation along with self-submitted weight measurements to ensure program integrity by providing visual verification that the beneficiary personally conducted the weight measurement, preventing potential fraud resulting from unauthorized individuals using shared household scales.

Finally, we acknowledge the support for including A1C measurements as accepted MDPP performance metrics. However, these comments are out-of-scope for this rule. MDPP remains a lifestyle intervention program focused on diabetes prevention through behavioral changes such as dietary change, physical activity, and weight loss. Weight loss serves as an appropriate outcome measure, as it directly

reflects the program's core objectives. Unlike A1C testing, which requires laboratory work, weight measurement is a less burdensome approach that maintains program scalability while supporting CMS' performance-based payment structure, which is designed to provide payments for achieving 5 and 9 percent weight loss milestones. The original DPP research demonstrated that achieving a 5 to 7 percent weight loss reduced diabetes risk by 58 percent,[327] validating weight as the primary success metric. CMS will continue to monitor feedback from interested parties and evaluate the demand for alternative performance metrics to ensure the program remains responsive to evolving clinical standards and participant needs.

3. Changes to §§ 410.79(f) and § 424.205(c)(10), (f)(2)(i), and (f)(5)

In the CY 2018 PFS final rule, we stated our intention to align MDPP with CDC DPRP Standards whenever possible (82 FR 53245). The CDC DPRP Standards have included virtual, online modalities and approaches since 2015[328]. MDPP has included in-person delivery of the Set of MDPP Services since it began serving beneficiaries in 2018. The MDPP expanded model emergency policy (85 FR 84831) broadened the delivery of the Set of MDPP services through synchronous distance learning to provide greater flexibility during the PHE for COVID-19, and later extended distance learning, and other related flexibilities through December 31, 2027, as part of the CY 2024 PFS final rule (82 FR 53249).

In the CY 2021 PFS final rule, we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by MDPP suppliers who offered in-person services (85 FR 84830) and maintained CDC DPRP "in-person" recognition (85 FR 84830 and 84831). In the CY 2024 PFS final rule, we extended flexibilities allowed during the PHE for COVID-19 for 4 years, or through December 31, 2027 (88 FR 79241). We also confirmed that suppliers who exclusively delivered MDPP services virtually via distance learning without maintaining in-person delivery capability were not permitted to furnish the Set of MDPP services because MDPP beneficiaries may elect to return to in-person services, and MDPP suppliers need to be able to accommodate their request (88 FR 79248).

The CY 2025 PFS final rule confirmed that only MDPP "in-person," "distance learning," and "in-person with a distance learning component" delivery modes are acceptable delivery modalities for MDPP

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[327] Diabetes Prevention Program (DPP) Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. Diabetes Care. 2002 Dec;25(12):2165-71. doi: 10.2337/diacare.25.12.2165. PMID: 12453955; PMCID: PMC1282458.
[328] 2015 CDC DPRP Standards: https://stacks.cdc.gov/view/cdc/44247.

during the Extended flexibilities period, as finalized in the CY 2024 PFS final rule (88 FR 79241). The CY 2025 PFS final rule did not include "Online" nor "combination with an online component" as accepted delivery modalities for MDPP. For the MDPP Extended flexibilities period, we finalized in the CY 2024 PFS final rule to limit virtual delivery to the CDC DPRP definition of ''distance learning'' (88 FR 79243). We stated that the MDPP Extended flexibilities do not include Online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''Online'' modality, including virtual make-up sessions (88 FR 79244). The 2024 CDC DPRP Standards allow for National DPP make-up sessions to be furnished using any delivery mode, including Online.[329]

The MDPP expanded model was certified as a primarily in-person program. Virtual-only providers include those that deliver the National DPP services solely by distance learning or Online delivery. Although "telehealth" is included in CDC's definition of distance learning, CMS stated in the CY 2017 PFS final rule (82 FR 53235) that the Set of MDPP services delivered via a telecommunications system, or other remote technologies do not qualify as telehealth services. Additionally, we have stated that through utilizing distance learning, participants may still interact with their Coach and other participants in their cohort in real-time, allowing for relationship building and peer support, unlike the Online modality which is delivered asynchronously (88 FR 79244).

We have responded to previous public comments requesting that CMS allow asynchronous delivery of MDPP and virtual-only providers to offer MDPP in previous rules (89 FR 98045). In past years, commenters have expressed that the exclusion of an asynchronous delivery modality is misaligned with the CDC DPRP Standards, which permit "Online" asynchronous participation. Suppliers have commented that the exclusion of asynchronous modality significantly limits program participation. Advocacy group members pursued legislation that would require CMS to open the MDPP to suppliers of asynchronous "Online" MDPP programs through the Prevent Diabetes Act. [330] in April 2024. Although this bill was not enacted into law, suppliers continue to encourage CMS to meet the demand for asynchronous delivery of MDPP. After the PHE went into effect in March 2020, more than 90 percent of all MDPP sessions were delivered virtually via distance learning. To date, average weight loss for MDPP

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[329] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.
[330] H.R. 7856 (118th): PREVENT DIABETES Act, https://www.govtrack.us/congress/bills/118/hr7856/text.

beneficiaries is 4.9 percent of starting body weight. Among beneficiaries that attend their sessions primarily in person, the average weight loss was 4.6 percent, compared with an average weight loss of 5.3 percent among those that attend sessions virtually via distance learning. [331]

We proposed adding paragraph (f) to 45 CFR 170.79 to test the addition of coverage of an Online delivery modality during the Online delivery period (until December 31, 2029). Consistent with the 2024 CDC DPRP Standards, organizations are required to submit a separate application for each delivery mode used to the CDC. This will result in a separate organization code (orgcode) for each delivery mode. Therefore, organizations are required to obtain an Online organization code from CDC prior to delivering Online sessions for MDPP.[332]

As referenced above, the MDPP expanded model was certified as a primarily in-person program, and CMS previously opposed inclusion of an asynchronous delivery modality for MDPP for various reasons. We consider the proposed change to include the Online, asynchronous delivery modality as an MDPP delivery modality a test during the Online delivery period. To evaluate the efficacy of Online delivery during the Online delivery period, beneficiary outcomes from asynchronous (that is, Online) will be evaluated to determine if this delivery modality reduces costs and improves quality. We continuously monitor MDPP trends and believe that the inclusion of Online delivery during the Online delivery period will build upon previous changes to introduce distance learning during the PHE for COVID-19 (85 FR 84830 through 84841) and respond to innovations in health care delivery and the increased provision of remote services. In addition, we anticipate that the inclusion of the Online delivery modality will promote beneficiary access to services, remove the barrier of beneficiaries having to wait for a cohort to start due to the on-demand nature of this proposed modality, build on the inclusion of the distance learning delivery modality, and align with the CMS Innovation Center Strategy to Make America Healthy Again by promoting evidence-based prevention, empowering people to achieve their health goals, and driving choice and competition for people.[333] In the CY 2024 PFS final rule, CMS reminded MDPP suppliers that

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[331] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.
[332] National Diabetes Prevention Program FAQ: Delivery Mode https://nationaldppcsc.cdc.gov/s/article/FAQ-Delivery-Mode-1526419438273#:~:text=Organizations%20may%20offer%20the%20program,Minutes%20in%20the%20DPRP%20Standards%20.
[333] CMS Innovation Center Strategy to Make America Healthy Again https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again

they are required to maintain capacity to deliver the MDPP Set of services in-person.[334] However, we proposed at § 410.79(f)(2) to explicitly not require MDPP suppliers to maintain in-person delivery capability during the Online delivery period. This will allow for distance learning and Online-only organizations to enroll in Medicare as an MDPP supplier and streamline the process to allow for Online delivery of the Set of MDPP services. In hopes of further increasing program participation among suppliers and beneficiaries and promoting alignment between MDPP and the 2024 CDC DPRP Standards, we proposed adding coverage of the delivery of the Set of MDPP services using the Online modality during the Online delivery period to test if outcomes, for MDPP beneficiaries, including weight loss, are similar to the in-person and distance learning delivery modalities.

Additionally, at § 410.79(f)(2)(i), we proposed that Online sessions must be furnished in a manner consistent with the DPRP Standards regarding program format, Coach interaction, and program intensity and duration to qualify for payment. Online sessions must be delivered 100 percent through the internet via smartphone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence ([AI]) Coach teaching the content. We proposed at § 410.79(f)(2)(i)(A) that Live Coach interaction must occur between MDPP beneficiaries and Coaches during the weeks when the beneficiary has engaged with content to qualify for payment. MDPP suppliers may not use AI or Machine Learning (ML) to replace Live Coach interaction.

Additionally, we proposed that weight collection procedures referenced in the MDPP expanded model emergency policy at § 410.79(e)(3)(iii)(C) as well as the proposed (c)(1)(ii) apply during the Online delivery period for MDPP services, as defined at § 410.79(b). Beneficiaries must submit weight measurements on the date on which the Online session is completed. We also proposed at § 410.79(f)(2)(i)(B) that MDPP suppliers must ensure safeguards are in place to ensure the accuracy of beneficiary weight measurements. These safeguards may include but are not limited to quality controls, diagnostic testing of hardware or software, and monitoring of trends (for example, rapid beneficiary

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[334] Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (88 FR 79249), Thursday November 16, 2023.https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other#page-79249.

weight loss within a short timeframe), are in place to ensure the accuracy of beneficiary weight measurements. For example, if organizations choose to use a website or mobile application to deliver the Set of MDPP services Online, integrations with hardware such as smart/Bluetooth™ scales may be used to collect beneficiary weight measurements. Scales may be set up to automatically transmit weight measurements directly to the MDPP supplier and MDPP suppliers may opt to perform data validation checks and flag suspicious entries or ensure necessary firmware updates are deployed to ensure the accuracy and/or security of such scales. As described in at § 410.79(f)(2)(i)(B), MDPP suppliers delivering the Set of MDPP services must ensure necessary technological safeguards to ensure the accuracy of weight collected through Bluetooth ™ scales, transmitted through an application, or utilizing any other means that do not involve direct Coach interaction or Coach review of photos/video. For instance, CMS expects organizations to ensure safeguards to avoid fraud, waste, and abuse (including but not limited to hardware or software errors and data manipulation) and organizations may be subject to audits to ensure compliance.

While CDC DPRP Standards define "combination with an Online component" as a yearlong National Diabetes Prevention Program Lifestyle Change Program (National DPP LCP) delivered as a combination of Online (non-live) with in-person and/or distance learning, we proposed that MDPP suppliers deliver MDPP via in-person, distance learning, in-person with a distance learning component, or Online modalities. While MDPP suppliers may offer synchronous and asynchronous modalities, they may not intermingle asynchronous (for example, Online) and synchronous (that is, In-Person, In-person with a distance learning component, and Distance learning) delivery modalities for individual beneficiaries. The Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, in-person, distance learning, or In-person with a distance learning component) or fully asynchronously (that is, Online). To evaluate the efficacy of the Online delivery modality during the Online Delivery Period, beneficiary outcomes from synchronous (that is, in-person, distance learning, or in-person with a distance learning component) delivery of the Set of MDPP services must be compared to beneficiary outcomes from asynchronous (that is, Online); therefore, these modalities must be delivered separately for individual beneficiaries in order to evaluate whether Online results, including weight loss, are similar to in-person and distance learning delivery modalities.

If organizations choose to provide the Set of MDPP services Online, we proposed that organizations must adhere to requirements consistent with CDC DPRP Standards regarding program format, Coach interaction, and program intensity and duration to qualify for payment, as described at § 410.79(f)(2)(i).[335] Specifically, we proposed during the Online delivery period at § 410.79(f)(2)(i)(D) that organizations must ensure that participants enrolled in self-paced programs engage with the content through use of one or more of the following: documented completion of videos/presentations and other learning modules in the application; knowledge checks (multiple choice or short answer); participant contributions to group discussions on a community board; and participant responses to the Coach via email, text message, or in-app messaging.

Though the 2024 CDC DPRP Standards indicate live lifestyle Coach interaction is required for Online delivery and should be offered to each participant during weeks when the participants have engaged with program content, we proposed that live Coach interaction must occur between the Coach and MDPP beneficiary during the weeks when the beneficiary has engaged with content to qualify for payment for that session at § 410.79(f)(2)(i)(A). Consistent with the CDC DPRP Standards, E-mails and text messages can count toward the requirement for live Coach interaction as long as there is bi-directional communication (that is, organizations may not simply send out an announcement via text or e-mail and count that as live coach interaction; the participant must have the ability to respond to and get support from the live coach) and both parties engage in some sort of communication. In alignment with CDC DPRP Standards, we proposed that Coaches be required to track beneficiary engagement and completion of Online modules. Additionally, proactive outreach by the Coach may be used to encourage session completion and reporting of weight. To promote consistency with the 2024 CDC DPRP Standards and to ensure that beneficiaries receive Live Coach interaction across delivery modalities, we proposed that MDPP suppliers may not require that beneficiaries initiate Coach interactions and MDPP suppliers may not use AI or machine learning (ML) to replace live coaching, as described at § 410.79(f)(2)(i)(A).We also proposed to revise § 424.205(c)(10) to allow the minimum number of

[335] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

required MDPP core sessions and core maintenance sessions to be delivered Online during the Online delivery period.

At § 424.205(c)(10)(i), we proposed to require 16 in-person, distance learning, or Online core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session. Next, at § 424.205(c)(10)(ii), we proposed to require one in-person, distance learning, or Online core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

We also proposed to amend § 424.205(f)(2)(i) to include the Online modality among acceptable session types for session documentation. We proposed at § 424.205(f)(5)(i) through (iv) to incorporate changes necessary for other proposed changes, including the addition of references directly at § 410.79(c)(1)(ii), and removal of references to "in person" in regard to how weight loss must be measured. These proposed changes provide greater clarity regarding the MDPP supplier's records in regard to claim submission for weight loss and are aligned with the proposed changes allowing for weight documented in a medical record.

We anticipate that beneficiaries will appreciate the option to participate in MDPP via the Online modality, which will expand beneficiary access to MDPP, reduce barriers to participation, and improve health outcomes. MDPP suppliers and advocacy groups will also appreciate the inclusion of the Online modality, as these entities have commented that the exclusion of the Online modality significantly limits program participation, particularly for beneficiaries living in areas without a nearby in-person MDPP delivery site (for example, rural areas) or access to transportation.

We proposed to amend §§ 410.79(f) and 424.205(c)(10), (f)(2)(i), and (f)(5). We solicited comments on these proposals. The following is a summary of the comments received and our responses.

Comment: Many commenters expressed support for adding coverage for asynchronous Online delivery of MDPP through December 31, 2029. Several commenters highlighted that Online delivery for MDPP would better align with CDC DPRP Standards and significantly increase program accessibility for beneficiaries who face barriers to attending synchronous sessions, including those with scheduling conflicts and transportation challenges. Many commenters noted that asynchronous, virtual delivery options align with modern healthcare delivery trends and could improve program participation.

Additionally, commenters supported the existing alignment of MDPP program requirements with the 2024 CDC DPRP Standards to obtain separate orgcodes for each distinct delivery mode, viewing this alignment as a way to enhance both program integrity and operational flexibility.

Response: We appreciate the support from commenters regarding the addition of Online delivery during the Online delivery period. This change aims to increase program participation. We are pleased that commenters recognize this alignment with the 2024 CDC DPRP Standards as providing operational flexibility to suppliers. After consideration of public comments received, we are finalizing §§ 410.79(f) and 424.205(c)(10), (f)(2)(i), and (f)(5) as proposed.

Comment: Some commenters opposed CMS' proposed requirement for live Coach interaction as a requirement for payment in Online delivery, stating that while CDC DPRP Standards require live Coach interaction, suppliers should not be denied payment for services rendered if beneficiaries fully engage with lesson content. Specifically, the commenters stated that this requirement creates administrative complexity and penalizes suppliers if participants complete lesson content but do not respond to follow-up outreach.

Response: We maintain that the live Coach interaction requirement is fundamental and integral to program success, as evidenced by its inclusion in all accepted delivery modalities for MDPP and directly aligns with CDC DPRP Standards. This requirement maintains program integrity and quality standards, ensuring Medicare beneficiaries receive comprehensive, evidence-based support to reduce type 2 diabetes risk.

Comment: Some commenters suggested that CMS implement caps of 1,000 beneficiaries per year (per MDPP supplier) for Online delivery during the Online delivery period to enable rigorous evaluation and prevent market destabilization, while others suggested limiting Online delivery of eligible suppliers to those with CDC DPRP full or full plus recognition to ensure only the most experienced virtual suppliers are eligible to participate. Several commenters expressed concern that without appropriate guardrails, large online entities could dominate the market and undermine local suppliers. These commenters noted that in-person and distance learning sessions provide valuable support for addressing social isolation and connecting participants to additional community services, benefits that purely Online delivery cannot replicate.

Response: The final rule tests the addition of coverage of an Online delivery modality during the Online delivery period (until December 31, 2029) without implementing participation caps. Our primary goal is to increase access to MDPP and enable as many eligible Medicare beneficiaries as possible to participate in and benefit from the program in their preferred session format. Implementing a cap of 1,000 Online delivery participants per organization per calendar year would be inconsistent with our goal to increase access to this program. Given that our estimates indicate that over 9 million FFS Medicare beneficiaries are eligible for MDPP, we believe removing barriers to participation is essential to maximize MDPP's public health impact. While we understand commenters' concerns, we do not anticipate that Online suppliers will saturate the market to such an extent that it would compromise our ability to evaluate program effectiveness or generalize findings across different supplier types.

Similarly, we acknowledge commenters' suggestions to limit Online delivery to organizations with CDC DPRP Full or Full-Plus recognition during the Online delivery period. While we recognize that organizations with Full or Full-Plus recognition have demonstrated substantial experience in delivering the National DPP Lifestyle Change Program, we believe that limiting participation to only these organizations would be inconsistent with our primary goal of increasing access to MDPP for as many Medicare beneficiaries and suppliers as possible. The CDC DPRP recognition system includes multiple recognition levels, all of which demonstrate that organizations meet established quality standards for delivering evidence-based diabetes prevention services. By allowing organizations with any level of CDC DPRP recognition to participate in Online delivery, we can expand the network of available MDPP suppliers and promote beneficiary choice. This approach supports our commitment to maximizing program reach while maintaining quality standards through the existing CDC recognition status framework. We will continue to monitor program performance across all supplier recognition status levels to ensure effective program delivery and beneficiary outcomes.

Finally, we acknowledge that in-person and distance learning delivery options provide valuable support for addressing social isolation and connecting participants to additional community services. The inclusion of Online delivery is intended to expand access to beneficiaries who may face barriers to in-person or distance learning participation, such as transportation challenges, mobility limitations, or geographic constraints. Beneficiaries who prefer live, group-based MDPP programs for socialization

benefits may continue to choose in-person or distance learning participation, as these remain accepted delivery modalities for MDPP. Providing beneficiaries with a variety of participation formats for MDPP ensures program accessibility while preserving the socialization benefits that participants value.

Comment: Some commenters requested that CMS allow a combination of delivery methods rather than restricting participants to single modalities as proposed at § 410.79(f)(2)(i)(C), to allow for broader reach. Another commenter suggested that restricting a combination of delivery modalities may create selection bias during the evaluation period, rendering evaluation results non-generalizable.

Response: After careful consideration of public comments, we are finalizing the proposal at §410.79(f)(2)(i)(C) that MDPP suppliers may not mix delivery modalities by billing for a combination of Online, In-Person, and Distance learning sessions during the Online delivery period. The Set of MDPP services must be delivered to individual beneficiaries either as Online sessions or fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component) during the Online delivery period. While we acknowledge commenters' concerns that restricting participants to a single modality may limit flexibility, we believe that maintaining separate delivery modalities is essential for a rigorous evaluation during the Online delivery period. By evaluating synchronous and asynchronous modalities separately, CMS can obtain data that will allow for more definitive conclusions about the effectiveness of each modality, ultimately informing future program improvements that best serve Medicare beneficiaries.

We appreciate commenters' concern about maintaining rigorous evaluation and protecting community-based MDPP suppliers who predominantly deliver the program in-person. We recognize that many beneficiaries aged 65 and older value in-person delivery for its socialization benefits, suggesting sustained demand for face-to-face interaction in healthcare programs. The MDPP expanded model was certified as a primarily in-person program. Competition between delivery modalities is driven by beneficiary choice and demand, and offering a variety of MDPP delivery modalities aligns with the CMS Innovation Center Strategy to Make America Healthy Again by driving choice and competition for people.[336] We recognize the continued demand for in-person and distance learning MDPP sessions, and

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[336] CMS Innovation Center Strategy to Make America Healthy Again https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again.

are introducing Online delivery to increase supplier capacity and availability for beneficiaries who choose to participate asynchronously. Beneficiaries inclined to participate In-person or via Distance learning will retain those participation options. Suppliers reserve the option to deliver services in-person and via distance learning. Online delivery will provide an additional option available to MDPP suppliers if they choose to utilize this delivery format to reach a larger number of eligible beneficiaries. CMS does not expect suppliers to modify their existing business models to offer all accepted delivery modalities for MDPP. We will continue to monitor program implementation and supplier participation to ensure robust evaluation and program delivery across modalities.

Comment: Some commenters noted that the Online delivery period described at § 410.79(f) from January 1, 2026, to December 31, 2029 is temporary in nature, and that suppliers may face resource challenges while implementing delivery models under temporary authorization.

Response: We acknowledge commenters' concerns regarding challenges that MDPP suppliers, particularly community-based organizations, may face when implementing Online delivery methods under temporary authorization. At § 410.79(f) we proposed to implement the Online Delivery Period from January 1, 2026, to December 31, 2029, to evaluate whether the Online modality produces similar outcomes for MDPP beneficiaries compared to In-person and Distance learning modalities. During this period, MDPP suppliers may deliver services using the Online modality. This test period will allow CMS to gather data to evaluate Online delivery modality, and CMS will monitor results that may inform future policy decisions.

We are finalizing the definition and timeframe of the Online delivery period as proposed to facilitate program evaluation.

Comment: Some commenters requested enhanced CMS monitoring efforts for Online delivery to ensure successful implementation and effective service delivery.

Response: In response to public comments requesting enhanced monitoring efforts for Online delivery to ensure successful implementation—we emphasize that MDPP suppliers must adhere to the established session structure described at § 424.205(c)(10)(i) to qualify for payment for MDPP sessions. Regardless of delivery modality, MDPP sessions structure consists of up to 22 intensive sessions furnished over 12 months, which includes 16 core sessions delivered weekly over 6 months followed by

core maintenance sessions delivered monthly in the following 6 months. These requirements align with "Requirements for Pending, Preliminary, Full, and Full Plus Recognition," described in the 2024 CDC DPRP Standards.[337] MDPP suppliers must ensure beneficiaries complete 1 core session per week, or every 7 calendar days.

At § 424.205(c)(10)(ii), we proposed to require 1 in-person, distance learning, or Online core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period. This established session structure is critical for accurately measuring program outcomes, particularly weight measurements that are tied to session completion. MDPP suppliers are responsible for ensuring compliance with CMS-established session structure requirements when delivering sessions through Online delivery. For example, for Online delivery, MDPP suppliers may consider implementing content module releases on a weekly basis to prevent beneficiaries from completing multiple sessions within timeframes that are not consistent with the required session structure. MDPP suppliers may also consider Coach outreach strategies to remind beneficiaries of the established session structure and encourage consistent participation as they progress through MDPP sessions asynchronously.

In response to comments requesting enhanced monitoring for Online delivery and upon further review of existing regulations at § 410.79(b), we have determined that current requirements for make-up sessions do not adequately address Online delivery. The clarification of make-up session requirements serves as a critical safeguard against potential program integrity issues, including the risk of beneficiaries accessing multiple sessions within compressed timeframes that would be inconsistent with the established session structure. Make-up sessions for Online delivery were referenced in the proposed rule at § 410.79(f)(2)(i)(C), which states the Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, in-person, distance learning, or in-person with a distance learning component) or fully asynchronously (that is, Online).

Specifically, at § 410.79(d)(1), we are revising existing requirements which state "an MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person or distance learning delivery." We are revising this

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[337] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

language to indicate that Online delivery is also an accepted delivery modality for make-up sessions by specifically stating that "an MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person, distance learning, or Online delivery." We emphasize that the existing requirements at § 410.79(d)(1)(i), (ii), and (iii) describe make-up sessions. Specifically, § 410.79(d)(1)(i) states that the curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed. Section 410.79(d)(1)(ii) states that the MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and (iii) the MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week. Additionally, existing requirements at § 410.79(d)(2) remain unchanged and describe requirements for virtual make-up sessions. Specifically, § 410.79(d)(2)(i) states virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions; § 410.79(d)(2)(ii) states that an MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request. Section 410.79(d)(1)(iii)(A) states an MDPP supplier may offer an MDPP beneficiary no more than 4 virtual make-up sessions within the core services period, of which no more than 2 virtual make-up sessions are core maintenance sessions. These revisions provide necessary clarification to ensure that requirements for Online delivery, including make-up sessions, are represented under this regulation. In direct response to public comments emphasizing the need for enhanced CMS monitoring of Online delivery, these clarifications establish clear parameters that promote effective oversight of program compliance and prevent beneficiaries from circumventing the established MDPP session structure, such as completing multiple sessions in rapid succession.

Comment: A commenter requested that CMS should require all asynchronous MDPP programs to meet section 508 compliance standards to ensure equal access to Online delivery.

Response: In response to the comment regarding section 508 compliance for Online delivery, we emphasize that the application of section 508 of the Rehabilitation Act, which requires Federal agencies to make their electronic and information technology accessible to people with disabilities, is unaffected.[338]

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[338] Information and Communication Technology Revised 508 Standards and 255 Guidelines https://www.access-board.gov/ict/

The CDC National Diabetes Prevention Program curriculum and materials[339] are designed to be section 508 compliant. Adherence to section 508 standards is part of an organization's existing legal obligations when providing services that involve Federal programs or funding. We believe that referencing existing legal requirements in this rule will be redundant, as these compliance obligations are already established through Federal law and apply to all relevant organizations.

Comment: Many commenters supported adding coverage for Online delivery of MDPP through December 31, 2029, with many offering specific recommendations for the rollout of this delivery method. The top suggestion from commenters was for CMS to implement a robust beneficiary outreach campaign, including partnering with providers, to increase the visibility of the program with patients and clinicians. Commenters noted that CMS should generate and distribute more provider and member-directed materials that describe the MDPP program, its benefits, and coverage. Commenters also suggested that CMS should actively educate providers that MDPP is a preventive service without cost-sharing and does not require a referral or prescription. They noted that beneficiaries looking for MDPP resources often encounter directories reflecting only In-person delivery options, with map-based listings that exclude virtual (that is, distance learning, Online delivery) options. Several commenters requested that CMS update Medicare.gov and related beneficiary-facing resources to include virtual suppliers in provider directories. Other commenters suggested that CMS should streamline enrollment and provide technical assistance for smaller suppliers. Finally, a commenter emphasized the potential benefit of leveraging pharmacies for MDPP, noting the demonstrated impact pharmacists contribute to diabetes prevention and management, and encouraging CMS to use pharmacy sites and teams to expand access.

Response: We appreciate commenters' suggestions related to the rollout of Online delivery. We will ensure efforts to enhance beneficiary and provider awareness of MDPP and will support prospective and existing MDPP suppliers through outreach efforts, website and resource updates, and technical assistance offerings. We will continue to explore partnerships to expand access and ensure successful implementation of this important preventive benefit. Additionally, we appreciate the commenters' input regarding expanding pharmacist participation in MDPP. Pharmacies are able to enroll as MDPP

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[339] CDC National Diabetes Prevention Program PreventT2 Curriculum and Handouts https://www.cdc.gov/diabetes-prevention/php/lifestyle-change-resources/t2-curriculum.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.

suppliers under existing program requirements, and several pharmacies are successfully delivering the MDPP to Medicare beneficiaries at this time.

Comment: Many commenters expressed support for clarifying that MDPP suppliers are not required to maintain in-person delivery capability during the Online delivery period through December 31, 2029 at § 410.79(f)(2). Many commenters stated that this clarification would reduce operational burdens on suppliers, particularly those specializing in virtual delivery models. Many commenters noted that this policy change would allow suppliers to ensure beneficiary access to the program.

Response: We appreciate the supportive comments regarding the clarification at § 410.79(f)(2) that MDPP suppliers are not required to maintain in-person delivery capability during the Online delivery period through December 31, 2029. This policy aims to reduce operational burdens on suppliers while ensuring continued beneficiary access to MDPP through a variety of delivery modalities, including Online delivery. Due to strong support for the proposal at § 410.79(f)(2) to explicitly not require MDPP suppliers to maintain in-person delivery capability during the Online delivery period to allow for distance learning and Online-only organizations to enroll in Medicare as an MDPP supplier and streamline the process to allow for Online delivery of the Set of MDPP services, we are finalizing this policy as proposed.

4. Changes to § 414.84

MDPP, as defined at § 410.79(b), consists of up to 16 sessions offered during the core session period (Months 1 to 6) and 6 monthly maintenance sessions offered during the core maintenance session interval period (Months 7 to 12), (collectively the "core services period"). While MDPP has an attendance-based fee-for-service payment structure as finalized in the CY 2024 PFS final rule (88 FR 79251), MDPP suppliers are also rewarded for successful outcomes for beneficiaries (weight loss), motivating them to not only retain participants, but also deliver a high-quality program that achieves better outcomes through performance-based payments. The fee-for-service payment structure finalized in the CY 2024 PFS final rule (88 FR 79251) added a distance learning HCPCS G-code, taking into consideration the Extended flexibilities.

We proposed edits throughout § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text to update language to include all accepted MDPP delivery modes for performance goals in which beneficiaries achieve weight loss milestones. We also proposed adding paragraph (c)(3) to

indicate payment for Online delivery, including the inclusion of a new HCPCS G-code, G9871, for Online delivery (Behavioral counseling for diabetes prevention, online, 60 minutes). Finally, we proposed redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively and revising the redesignated paragraph (c)(4)(ii) to include a payment rate for a core session or core maintenance session furnished Online during the Online delivery period ($18).

Table B-E1 displays the proposed CY 2026 MDPP payment structure for the Set of MDPP services delivered Online.

TABLE B-E1: MEDICARE DIABETES PREVENTION PROGRAM (MDPP) EXPANDED MODEL CALENDAR YEAR (CY) 2026 ONLINE PAYMENT STRUCTURE

HCPCS G-Code	Payment Description*	CY 2026
G9871	Behavioral counseling for diabetes prevention, online, 60 minutes	$18
G9880	5 percent WL Achieved from baseline weight	$153
G9881	9 percent WL Achieved from baseline weight	$ 27
G9888	Maintenance 5 percent WL from baseline in months 7-12	$8

Note: Medicare pays up to 22 sessions. Online sessions billed with code G9871cannot be combined with G9886 or G9887, in a 12-month period:
Months 1-6: one Online session every week (up to 16)
Months 7-12: one Online session every month (up to 6)
Months 7-12, once participant achieves 5 percent WL, suppliers delivering the Set of MDPP services Online may submit Maintenance of 5 percent WL claim with attendance claim (G9888 + G9871). Medicare will pay for Maintenance 5 percent WL up to 6 times in months 7-12.

As indicated in Table B-E1, performance payments for 5 percent weight loss achieved from baseline weight (G9880) and 9 percent weight loss achieved from baseline weight (G9881) will remain the same regardless of delivery modality for MDPP. For each beneficiary, MDPP suppliers must either bill claims with G9886, G9887, a combination of G9886 and G9887, or G9871. The proposed G9871 for behavioral counseling for diabetes prevention, online, 60 minutes is for the Set of MDPP services delivered Online, asynchronously. The existing G9886, behavioral counseling for diabetes prevention, in-person, group, 60 minutes, and G9887, behavioral counseling for diabetes prevention, distance learning, 60 minutes are delivered synchronously. Therefore, we proposed that for each beneficiary, suppliers may not bill for the Set of MDPP services that were delivered through a combination of synchronous and asynchronous delivery modalities. Specifically, for MDPP beneficiaries, MDPP suppliers may not bill for Online Sessions as well as In-Person or Virtual Sessions during the Online delivery period. The Set of MDPP services must be delivered to individual beneficiaries as exclusively Online sessions (fully asynchronous) or exclusively In-person, distance learning, or In-person with a distance learning component sessions (fully synchronous). To evaluate the efficacy of Online delivery during the Online

Delivery Period, beneficiary outcomes from synchronous (that is, In-person, Distance learning, or In-person with a distance learning component) delivery of the Set of MDPP services must be compared to beneficiary outcomes from asynchronous (that is, Online), therefore, these modalities must remain mutually exclusive for individual beneficiaries. While the 2024 CDC DPRP Standards define "Combination with an online component" as sessions that are delivered as a combination of online (non-live) with in-person or distance learning, this will not be an accepted delivery modality for MDPP while Online delivery is being tested through December 31, 2029.

In summary, we proposed to amend § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text; adding paragraph (c)(3); redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively; and revising the redesignated paragraph (c)(4)(ii). We sought comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters noted that the proposed Online delivery payment rate at $18 per session represents a 28 percent reduction that translates to 21 percent lower maximum program payments, compared to $26 for in-person and distance learning modalities, despite evidence that virtual delivery achieves similar program outcomes.

Many comments emphasized that while virtual care has the potential to improve health outcomes at lower overall costs, CMS should ensure Online delivery suppliers receive compensation that accounts for their unique operational costs. Some commenters emphasized that virtual MDPP providers face significant upfront investments, particularly in technology platforms and medical-grade equipment such as scales for MDPP beneficiaries. Some commenters requested that CMS include the cost for cellular-enabled weight scales to beneficiaries in the proposed payment rate for Online delivery, stating that these devices enable continuous data collection and reliable at-home weight tracking.

Another commenter suggested that CMS restructure payments for Online delivery to tie compensation directly to weight loss milestones, such as $500 for 5 percent weight loss and $268 for 9 percent loss rather than tying payments to lesson completion, or implementing a bundled payment model similar to Maryland Medicaid's approach with higher upfront enrollment payments to offset device distribution costs, reduced per-session fees, and maintained outcome-based bonuses.

Response: We appreciate input regarding payment parity for Online delivery. We proposed at § 414.84 (c)(3) to indicate payment for Online delivery, including the inclusion of a new HCPCS G-code, G9871. The proposed $18 payment rate for G9871 (Behavioral counseling for diabetes prevention, online, 60 minutes) was established through a comprehensive analysis of expected service costs informed by market research. This rate reflects the unique operational characteristics of Online delivery, including reduced overhead costs due to the elimination of physical location requirements during the Online delivery period, while maintaining the required live Coach interaction associated with each session. The rate was benchmarked against comparable healthcare services and market rates for similar digital health interventions, considering that Coaches provide 1 full hour of interaction with beneficiaries through in-person and distance learning modalities, whereas Online sessions involve reduced direct Coach interaction time per participant per week. The requirement for qualified Coaches to provide live, personalized support to each beneficiary justifies the established rate structure. Additionally, when determining the $18 rate, CMS referenced HCPCS code 98016 for virtual check-ins and e-visits, which is slightly less than $18, as part of the broader market analysis that informed the proposed rate. Online delivery offers increased scalability and financial viability for MDPP suppliers by eliminating the need to wait for group cohorts to form, allowing for rolling enrollment where beneficiaries can begin the program immediately—unlike in-person and distance learning delivery modalities that strive to achieve full group capacity prior to program delivery. We believe the proposed payment rate for G9871 appropriately reflects the value and costs associated with Online delivery at this time. Therefore, we are finalizing the proposed changes to § 414.84 (c)(3) to indicate payment for Online delivery, including the inclusion of a new HCPCS G-code, G9871.

We appreciate commenters' feedback regarding the technology costs associated with virtual MDPP delivery, particularly concerning cellular-enabled weight scales and other medical-grade equipment. However, after careful consideration, we are not revising the MDPP payment methodology to separately account for cellular-enabled weight scales or similar technology costs. Under § 424.210, MDPP suppliers already have the flexibility to provide Beneficiary Engagement Incentives (BEIs) to

support program goals.[340] While we acknowledge that cellular-enabled scales may facilitate weight tracking, the regulation already permits the provision of technology that advances the clinical goal of weight loss as a BEI. We encourage virtual MDPP suppliers to leverage MDPP's existing BEI guidance to support beneficiary success. We will continue to monitor the implementation of MDPP services and may consider future refinements to the payment methodology based on demand, program experience, and outcomes data.

Additionally, we acknowledge the commenter's suggestion regarding lump outcome-based payments for 5 and 9 percent beneficiary weight loss. After careful consideration, we maintain its current approach of tying performance payments to session completion. Through the CY 2024 PFS final rule (88 FR 79251), CMS responded to feedback from interested parties regarding payment structure complexity by introducing FFS attendance-based payments while preserving performance payments associated with beneficiary weight loss. This revision aligned MDPP payments with similar Medicare preventive services, such as IBT and DSMT, and increased efficiency by reducing HCPCS G-codes from 15 to 6 to encourage streamlined claim submission. While we recognize the appeal of lump outcome-based payments, the current payment structure ensures program integrity and prevents fraud by associating weight loss outcomes with a preventive service. Additionally, the current payment structure results in more frequent payments to MDPP suppliers in an effort to promote supplier retention. We will continue to monitor the effectiveness of this approach and welcome continued stakeholder feedback on program improvements.

Comment: Outside the scope of the proposed changes to MDPP regarding payment for Online delivery, multiple commenters stated that the current payment rates for G9886 (Behavioral counseling for diabetes prevention, in-person, group, 60 minutes) and G9887 (Behavioral counseling for diabetes prevention, distance learning, group, 60 minutes) do not reflect the true costs of service delivery. These commenters expressed concerns about the existing MDPP payment rates being insufficient to sustain program operations including Coach training and retention, marketing, recruitment, HIPAA and CMS compliance requirements, billing and reporting obligations, and program oversight expenses. The most frequently cited recommendation was to raise payment rates to at least $40 per In-person or distance

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[340] § 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-424/subpart-I/section-424.210.

learning session, with several commenters specifically requesting this amount to achieve parity with Diabetes Self-Management Training (DSMT) and Intensive Behavioral Therapy (IBT) programs, while another commenter requested at least a 20 percent increase to all attendance and weight-loss milestone payments to cover real operating costs such as participant recruitment, Coach training and retention, marketing, and data reporting requirements. Some commenters requested that CMS adopt a Relative Value Unit (RVU)-based approach to better account for suppliers' work, practice expenses, and malpractice costs when determining reimbursement rates. These commenters highlighted that in-person and distance learning delivery modalities require substantially higher labor and operational costs compared to Online delivery, stating that the proposed $8 differential between Online ($18) and synchronous delivery ($26) inadequately reflects these cost disparities. Another commenter provided a recommendation that CMS allow MDPP to be integrated with primary care services by permitting it to be billed as an add-on G-code alongside same-day advanced primary care management and incorporating an administrative component into the reimbursement structure.

Response: In response to comments outside of the scope of the proposed rule regarding MDPP payment rates for in-person and distance learning compared to DSMT and IBT, we clarify that MDPP payment rates do not provide a direct comparison to these programs due to fundamental differences in program structure, requirements, and delivery methods, which justify MDPP's payment methodology.

MDPP and DSMT serve distinct populations and purposes within Medicare's approach to diabetes care. MDPP is a lifestyle intervention program designed for Medicare beneficiaries with prediabetes who are at risk of developing Type 2 diabetes, focusing on structured lifestyle changes such as weight loss, increased physical activity, and dietary change. DSMT is for Medicare beneficiaries who have already been diagnosed with Type 1 or Type 2 diabetes, providing training on how to effectively manage a beneficiary's existing condition. MDPP emphasizes prevention through lifestyle modification in a group setting, while DSMT can be delivered individually or in a group setting.[341]

For MDPP, Coaches must be trained according to the CDC Diabetes Prevention Recognition Program Standards.[342] No additional clinical credentials are required. On the other hand, DSMT providers

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[341] Diabetes Self-Management Training https://www.medicare.gov/coverage/diabetes-self-management-training.
[342] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

must meet the National Standards for Diabetes Self-Management Education and Support.[343] DSMT providers should also be accredited through a CMS-certified accrediting organization and must be trained in diabetes care and education. Additionally, MDPP does not require a provider referral for participation, while DSMT services require a referral from the physician, nurse practitioner (NP), physician assistant (PA), or certified nurse specialist (CNS) who's treating the patient for diabetes.[344]

CMS covers intensive behavioral therapy for obesity (IBT), for the prevention or early detection of illness or disability. IBT counseling must be furnished by a qualified primary care physician or other primary care practitioner in a primary care setting. IBT definitions for "primary care physician" and "primary care practitioner" are consistent with existing sections 1833(u)(6), 1833(x)(2)(A)(i)(I) and 1833(x)(2)(A)(i)(II) of the Act).[345]

Unlike IBT for Obesity, MDPP may currently be furnished in a variety of community settings, administrative locations, or virtually. Additionally, MDPP Coaches must be trained according to the CDC DPRP Standards but are not required to maintain additional clinical credentials. While MDPP offers a variety of delivery modalities for up to 22 sessions in a 12-month period, IBT must be furnished face-to-face with the following session format over a 12-month period: one face-to-face visit every week for the first month; one face-to-face visit every other week for months 2 to 6; and one face-to-face visit every month for months 7 to 12, if the beneficiary meets the 3 kg weight loss requirement.[346]

MDPP, DSMT, and IBT for Obesity have different program requirements and coverage rules under Medicare. MDPP's requirements regarding Coach qualifications, group format, and flexible delivery options justify the current payment rate for In-person and Distance learning MDPP sessions. The Medicare procedure codes and national average payment rates for the DSMT claim are G0108 – DSMT, individual, per 30 minutes ($53.57) and G0109 – DSMT, group (2 or more), per 30 minutes ($15. 39). The national average reimbursement rates for procedure codes required by Medicare for the IBT for Obesity claim are G0447 for individual, face-to-face obesity counseling, 15 minutes ($31.70) and G0473

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[343] 2022 National Standards for Diabetes Self-Management Education and Support. *Diabetes Care* 1 February 2022; 45 (2): 484–494. https://doi.org/10.2337/dc21-2396.
[344]Provider Information on Medicare Diabetes Self-Management Training https://www.cms.gov/files/document/mln909381-provider-information-medicare-diabetes-self-management-training.pdf.
[345]Compilation of the Social Security Laws, Part E—Miscellaneous Provisions.
DEFINITIONS OF SERVICES, INSTITUTIONS, ETC. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm#act-1861-r.
[346] Medicare Coverage Database National Coverage Determination (NCD) Intensive Behavioral Therapy for Obesity https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=353.

for group counseling, 30 minutes ($11 to $13 across MACs).[347] The procedure codes currently required by Medicare for MDPP are G9886 – Behavioral counseling for diabetes prevention, in-person, group, 60 minutes ($26), and G9887 – Behavioral counseling for diabetes prevention, distance learning, group, 60 minutes ($26).[348]

As a group-based preventive service, the financial viability of MDPP programs is directly dependent on beneficiary participation. To ensure sustainability, it is strongly encouraged that organizations offering MDPP services maintain full group capacity. This strategy is critical because the group-based nature of MDPP means that suppliers must achieve adequate participant enrollment volume to make the program economically viable while maintaining the quality and effectiveness that MDPP's structured group format is designed to deliver.

We acknowledge the suggestions to adopt an RVU-based approach for MDPP reimbursement and to allow MDPP to be integrated with primary care services by permitting it to be billed as an add-on G-code alongside same-day advanced primary care management and incorporating an administrative component into the reimbursement structure. However, we believe MDPP's current FFS and performance-based methodology is most appropriate. Unlike traditional physician services using RVUs, MDPP focuses on specific health outcomes over time. MDPP's payment structure is designed to incentivize measurable outcomes such as 5 and 9 percent weight loss.

Comment: A commenter requested that CMS add diabetes-specific medically tailored meal benefits to MDPP.

Response: We acknowledge commenters' feedback regarding the addition of medically tailored meal benefits to MDPP. At § 424.210, MDPP suppliers have the flexibility to provide Beneficiary Engagement Incentives (BEIs) to support program goals.[349] Since medically tailored meals are considered a BEI, we are not revising the MDPP payment methodology to separately account for medically tailored meals at this time.

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[347]License for Use of Current Procedural Terminology, Fourth Edition ("CPT®"). https://www.cms.gov/medicare/physician-fee-schedule/search.
[348]Medicare Diabetes Prevention Program (MDPP) Expanded Model Calendar Year (CY) 2025 Payment Rates https://www.cms.gov/files/document/mdpp-cy2025-hpcs-g-codes.pdf.
[349]§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-424/subpart-I/section-424.210.

Comment: No public comments were received regarding changes at § 414.84, in which we proposed redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively.

Response: While we did not receive public comments regarding this redesignation, upon further review, we have identified that current requirements at redesignated (c)(5) do not adequately address same-day make-up sessions delivered Online. The clarification of make-up session requirements serves as a critical safeguard against potential program integrity issues, including the risk of beneficiaries accessing multiple sessions within compressed timeframes that would be inconsistent with the established session structure. To ensure regulatory clarity, we are finalizing revisions to existing requirements at redesignated paragraph (c)(5) which currently state "Current Procedural Terminology (CPT) Modifier 76 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session." We are revising this language to include the new G-code for Online delivery, G9871 (Behavioral counseling for diabetes prevention, online, 60 minutes), among the HCPCS codes for same-day make-up sessions by specifically stating that "Current Procedural Terminology (CPT) Modifier 76 (repeat services by same physician) must be appended to any claim for G9886, G9887, or G9871 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session."

E. Medicare Prescription Drug Inflation Rebate Program

1. Background

a. Overview of the Medicare Prescription Drug Inflation Rebate Program

Sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A the Act by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a "Part B rebatable drug," in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B.

Section 11102 of the IRA added section 1860D-14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period that began on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug, which is calculated as set forth in section 1860D-14B(b)(2) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1860D-14B(b)(3) of the Act. Section 1860D-14B(g)(1)(A) of the Act defines a "Part D rebatable drug," in part, as a drug or biological described at section 1860D-14B(g)(1)(C) of the Act that is a "covered Part D drug" as that term is defined in section 1860D-2(e) of the Act. The definition of a Part D rebatable drug includes drugs approved under

a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act, drugs approved under an abbreviated new drug application under section 505(j) of the FD&C Act that meet certain sole source criteria described at sections 1860D-14B(g)(1)(C)(ii)(I) through (IV) of the Act, and biologicals licensed under section 351 of the Public Health Service Act, including biosimilars.

The IRA sets forth different parameters for determining rebates under the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. For the rebates owed, for each calendar quarter beginning on or after January 1, 2023, the manufacturer of a Part B rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from CMS, to pay a rebate into the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount (calculated as set forth in section 1847A(i)(3)(C) of the Act) for an applicable calendar quarter. In contrast, for each 12-month applicable period beginning on or after October 1, 2022, the manufacturer of a Part D rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from CMS, to pay a rebate into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund if the amount of the AnMP (calculated as set forth in section 1860D-14B(b)(2) of the Act) exceeds the inflation-adjusted payment amount (calculated as set forth in section 1860D-14B(b)(3) of the Act). For invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, CMS must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, CMS had until September 30, 2025, to invoice manufacturers for rebates. In contrast, under section 1860D-14B(a) of the Act, CMS must report rebate amounts to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period, except that for the first two applicable periods (that is, October 1, 2022, to September 30, 2023, and October 1, 2023, to September 30, 2024), CMS has until December 31, 2025, to invoice manufacturers for Part D inflation rebates. Additionally, there are statutory differences in the inputs (that is, data sources) used to calculate the rebate amounts for Part B and Part D.

In the CY 2025 PFS final rule (89 FR 98228 through 98313), to implement sections 11101 and 11102 of the IRA, we codified these requirements and established other policies for the Medicare Part B

Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program (collectively referred to as the "Medicare Prescription Drug Inflation Rebate Program") in regulatory text at parts 427 and 428 under title 42, chapter IV of the Code of Federal Regulations for Part B and Part D, respectively.

b. Summary of Proposed Policies for the Medicare Prescription Drug Inflation Rebate Program

In the CY 2026 Physician Fee Schedule (PFS) proposed rule (90 FR 32633 through 32645), we proposed certain limited modifications to the policies for the Medicare Prescription Drug Inflation Rebate Program set forth in new parts 427 and 428 under title 42, chapter IV of the Code of Federal Regulations for Part B and Part D. Specifically, we proposed new policies for the Medicare Part B Drug Inflation Rebate Program as follows:

- Proposed § 427.302(c)(5) described how CMS will identify the payment amount benchmark quarter if data needed to calculate the payment amount in the payment amount benchmark quarter are not available.
- Proposed § 427.302(d)(1)(i) described CMS' method for calculating the payment amount in the payment amount benchmark quarter if a published payment limit is not available.
- Proposed § 427.302(d)(1)(ii) described CMS' method for calculating the payment amount in the payment amount benchmark quarter if there is no published payment limit and neither positive Average Sale Price (ASP) nor positive Wholesale Acquisition Cost (WAC) data are available in the ASP Data Collection System.

We also proposed new policies for the Medicare Part D Drug Inflation Rebate Program as follows:

- Proposed to use a claims-based methodology to implement § 428.203(b)(2), which provides that, for claims with dates of service on or after January 1, 2026, and for an applicable period, CMS will exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program.
- Proposed to establish a 340B repository to receive voluntary submissions from 340B covered entities of certain data elements from Part D claims for Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program.

We received public comments on the proposed provisions, comments on the Medicare Prescription Drug Inflation Rebate Program, and comments related to policies for which we did not make proposals. The following is a summary of these comments received and our responses on specific provisions.

Comment: A few commenters wrote in support of the Medicare Prescription Drug Inflation Rebate Program and a commenter wrote that any savings realized through the Medicare Prescription Drug Inflation Rebate Program should be reinvested into care delivery.

Response: We appreciate the commenters' feedback. We note that Part B and Part D inflation rebates paid by drug manufacturers are deposited into the Federal Supplementary Medical Insurance Trust fund in accordance with sections 11101(a) and 11102(a) of the IRA.

Comment: A commenter recommended that CMS establish that skin substitutes do not meet the statutory definition of a Part B rebatable drug that may be subject to inflation rebates under section 1847A(i) of the Act because they are not single source drugs or biological products. The commenter further noted that, thus far, CMS has excluded skin substitutes from the Medicare Part B Inflation Rebate Program as a matter of discretion.

Response: We appreciate the commenter's feedback regarding treatment of skin substitutes under the Medicare Part B Drug Inflation Rebate Program. We did not make any proposals associated with the treatment of skin substitutes for Part B inflation rebate calculations; therefore, this comment is considered to be out of scope of the proposed rule. At this time, skin substitutes are excluded from Part B inflation rebates as described at § 427.101(b)(5) and as finalized in the CY 2025 PFS final rule (89 FR 98235).

Comment: A commenter interpreted section 1847A(i)(2)(A) of the Act to expressly define a Part B rebatable drug as a drug for which payment is made under Medicare Part B and, therefore, in the view of the commenter, to exclude units of drugs furnished under Medicare Advantage (MA), also called Part C. Additionally, the commenter stated that units of rebatable drugs furnished under MA should be excluded from Part B rebatable drugs because they are not separately payable. The commenter suggested CMS continue to exclude MA units from the calculation of Part B rebates.

Response: We appreciate the commenter's suggestion regarding the treatment of MA units in the calculation of Part B rebates. We did not make any proposals associated with the treatment of MA units in

the calculation of Part B rebates; therefore, this comment is considered to be out of scope of the proposed rule. At this time and as stated in the CY 2025 PFS final rule (89 FR 98252), we will not include MA units in the calculation of Part B rebates due to operational considerations.

Comment: A commenter recommended CMS require the use of a non-340B claims modifier in addition to a 340B claims modifier, as applicable, for each unit billed under Part B and specify that accurate use of such a modifier is necessary for a claim to be considered complete and eligible for payment. The commenter also recommended CMS establish a clearinghouse to validate 340B units.

Response: We appreciate the commenter's suggestion regarding 340B claims modifiers in Part B. We did not make any proposals associated with 340B claims modifiers or a clearinghouse to validate 340B units in Part B; therefore, this comment is considered to be out of scope of the proposed rule. We refer the commenter to our responses to similar suggestions in the CY 2025 PFS final rule (89 FR 98249).

Comment: A commenter recommended CMS waive the inflation rebate for a subset of drugs in a currently in shortage status, such as out-of-stock drugs entirely unavailable to the market for at least one year and provided several suggestions for implementing a waiver process. The commenter stated that implementing a waiver process for such drugs would incentivize manufacturers to improve supply and resolve the shortage more quickly compared to current policy described in subpart E of part 427.

Response: We appreciate this commenter for their recommendations. We did not make any proposals associated with the rebate reductions for Part B rebatable drugs; therefore, this comment is considered to be out of scope of the proposed rule. However, we note that as stated in the CY 2025 PFS final rule (89 FR 98255), we will provide a variable reduction in the rebate amount based on the length of time a Part B rebatable drug is in the status of "currently in shortage" on an FDA shortage list during a calendar quarter, with the reduction decreasing over time. At this time, we will not provide a full waiver of the rebate amount for drugs currently in shortage on an FDA shortage list, as providing a full waiver of the rebate amount could further incentivize manufacturers to delay taking appropriate steps to resolve a shortage to avoid an obligation to pay rebates for an extended period.

After consideration of the public comments received, we are finalizing, with modifications, the proposed policies for the Medicare Prescription Drug Inflation Rebate Program.

2. Medicare Part B Drug Rebates for Single Source Drugs and Biological Products with Prices that

Increase Faster than the Rate of Inflation

a. Definitions (§ 427.20)

In the CY 2026 PFS proposed rule (90 FR 32634), we proposed to amend § 427.20 by removing the term "Billing and payment code FDA approval or licensure date". The term was not included in the CY 2025 PFS proposed rule. This term was intended to be used in the final rule at § 427.302(c), as evidenced by references to it in the final rule (89 FR 98244). Prior to publication of the final rule, however, we ultimately incorporated the definition text in place of the defined term, rendering the defined term inoperative, and we neglected to delete the unused term. To avoid any confusion arising from superfluous regulatory text, we proposed to remove the definition.

We did not receive public comments on the proposed revision, and we are finalizing as proposed the revision to § 427.20.

In the CY 2025 PFS final rule (89 FR 98579), we codified the definition of manufacturer in § 427.20 to have the meaning set forth in section 1847A(c)(6)(A) of the Act. As articulated in the CY 2025 PFS final rule (89 FR 98266), we will identify the manufacturer that is responsible for paying a rebate amount using the same approach used for identifying the manufacturer that is responsible for reporting ASP and Medicaid Drug Rebate Program (MDRP) data. In the CY 2026 PFS proposed rule (90 FR 32635), as a matter of operations, we clarified that CMS identifies the manufacturer with financial responsibility for the inflation rebate for a Part B rebatable drug by reviewing ASP data submissions for the current and historical reporting period(s) and the agency will also take into account, as applicable, manufacturer-identifying information in other CMS systems including MDRP.

We did not receive public comments on this issue. In operationalizing the Medicare Part B Drug Inflation Rebate Program for the first time, we have adopted this clarification with further refinements in our approach to ensure timely and appropriate manufacturer identification by taking into account, as applicable, manufacturer-identifying information in other government systems, including MDRP, and other public sources.

b. Drugs Covered as Additional Preventive Services (DCAPS)

Medicare Part B covers "additional preventive services," as defined under section 1861(ddd)(1) of the Act, that identify medical conditions or risk factors and that the Secretary determines are: (A)

reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force; and (C) appropriate for individuals entitled to benefits under Part A or enrolled under Part B. Section 1861(ddd)(2) of the Act states that, in making determinations under section 1861(ddd)(1) of the Act, the Secretary shall use the process for making National Coverage Determinations (as defined in section 1869(f)(1)(B) of the Act) in the Medicare program. Section 1833(a)(1)(W)(ii) of the Act provides for the payment for additional preventive services, including drugs.

On September 30, 2024, CMS established coverage of certain drugs as an additional preventive service under section 1861(ddd)(1) of the Act for the first time.[350] Such drugs covered as additional preventive services are referred to DCAPS, and we will use the term "DCAPS drug(s),"for ease of the reader.

As described at § 410.152(o)(3), CMS will determine the payment limit for the applicable billing and payment code for a DCAPS drug by applying the ASP methodology if ASP data is available (89 FR 98225). If ASP data is not available, then the payment limit would be determined using National Average Drug Acquisition Cost (NADAC) prices for the drug. If ASP data and NADAC prices are not available, the payment limit would be calculated using the Federal Supply Schedule (FSS) prices for the drug. If ASP data, NADAC prices, and FSS prices are not available, the payment limit would be the invoice price determined by the Medicare Administrative Contractor (MAC).

In the CY 2026 PFS proposed rule (90 FR 32635), we proposed to address whether DCAPS drugs are Part B rebatable drugs, as discussed in the CY 2025 PFS final rule (89 FR 98250). We explained that the current set of drugs covered as DCAPS drugs meets the definition of a Part B rebatable drug under section 1847A(i)(2) of the Act (90 FR 32635). Therefore, we proposed to identify DCAPS drugs as Part B rebatable drugs as defined in section 1847A(i)(2) of the Act. Under this proposal, we would calculate rebates for DCAPS drugs in alignment with the methodology described in §§ 427.300 through 427.402. Manufacturers of DCAPS drugs would receive reports of rebate amounts subject to the process and timing described in §§ 427.500 through 427.505.

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[350] See: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection, available at *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310*.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported CMS' proposal to designate DCAPS drugs as Part B rebatable drugs, stating that the proposal ensures that DCAPS drugs are treated consistent with other Part B drugs and will help control Medicare spending, ensure that price increases beyond inflation activate rebates, and protect Medicare enrollees from unnecessary cost increases.

Response: We appreciate the commenter for this support.

Comment: Some commenters opposed CMS' proposal to identify DCAPS as Part B rebatable drugs, stating that they believe CMS' interpretation of the IRA statute regarding DCAPS is inconsistent with prior policy to cover DCAPS as preventive services. Specifically, a few commenters noted that DCAPS are covered under Part B as "additional preventive services" under section 1861(ddd) of the Act rather than as separately payable drugs under section 1847A(i) of the Act. Therefore, a commenter noted it is inconsistent for CMS to cover DCAPS as an "additional preventive service" and still consider DCAPS to be eligible for inflation rebates as a "drug" under Part B. These commenters suggested CMS not to finalize this proposal and instead to clarify that DCAPS are not Part B rebatable drugs.

Additionally, a commenter expressed concern that CMS proposed this new policy without adequate interested parties' input, including soliciting the views of patients and clinicians, noting that this policy may have unintended consequences for treatment access. The commenter further stated that if CMS finalizes this proposed policy, CMS should provide greater transparency on the inclusion of DCAPS in the Part B inflation rebate requirements, but the commenter did not elaborate or provide an example.

Response: We appreciate commenters' feedback. We disagree with the suggestion that it is inconsistent to cover DCAPS drugs as "additional preventive services" and still considers DCAPS drugs to be Part B rebatable drugs. We maintain that the current set of drugs covered as DCAPS drugs meets the definition of a Part B rebatable drug under section 1847A(i)(2) of the Act. This definition does not exclude drugs on the basis that they are covered as additional preventive services under section 1861(ddd)(1) of the Act. Therefore, we will identify DCAPS drugs as Part B rebatable drugs as defined in section 1847A(i)(2) of the Act and calculate rebates for DCAPS drugs in alignment with the methodology described in §§ 427.301 through 427.402.

In response to the comment regarding interested parties' input, we believe the 60-day comment period for the CY 2026 PFS proposed rule offered interested parties with sufficient time to provide input on this proposal, including on any potential unintended consequences regarding treatment access. We do not have sufficient information regarding the commenter's concerns about providing greater transparency on the inclusion of DCAPS drugs in the Part B inflation rebate requirements to provide a response. However, we note that interested parties may continue to provide input via the CMS IRA mailbox (*IRARebateandNegotiation@cms.hhs.gov*), which CMS established to receive queries related to the implementation of the Medicare Part B and Part D Drug Inflation Rebate Programs and the Medicare Drug Price Negotiation Program.

Comment: A commenter expressed concern that operationalizing Part B inflation rebates for DCAPS drugs could present challenges because the Part B inflation rebate calculation is based on the ASP-based payment methodology and ASP reporting for DCAPS drugs is voluntary. This commenter recommended that if CMS finalizes this policy as proposed, CMS should explicitly clarify that all Part B 340B claims modifier requirements apply to DCAPS drugs and that CMS should periodically assess the accuracy of the 340B claims modifier reporting for DCAPS drugs to ensure that covered entities are complying.

Response: We appreciate the commenter's concern about operationalizing this policy and acknowledge that ASP reporting for manufacturers of DCAPS drugs is voluntary. We encourage DCAPS drugs manufacturers to submit ASP data to CMS. As previously stated, (89 FR 98223), we continue to believe that ASP-based payment limits are the most accurate drug pricing methodology that is available to CMS. For these same reasons, we believe that using voluntarily reported ASP data is appropriate and there is available pricing information to warrant their inclusion at this time. Additionally, ASP data are available for some NDCs for the current set of DCAPS drugs and in instances when ASP data are not available, we will use WAC price data from other public sources. We reiterate that we will calculate rebates for DCAPS drugs in alignment with the methodology described in §§ 427.301 through 427.402. Regarding application of 340B claim modifier requirements for DCAPS drugs, in accordance with the December 14, 2023 Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier program guidance, we require all 340B covered entities to report the "TB" modifier, as applicable, on claim lines

for separately payable DCAPS drugs. CMS will monitor the extent to which the 340B modifier is utilized on Part B claims for 340B-acquired DCAPS drugs.

After consideration of public comments, we have adopted this clarification.

c. Billing Units That Are Packaged Into the Payment Amount for an Item or Service And Are Typically Not Separately Payable

Section 1847A(i)(3)(B)(ii)(II) of the Act requires that units that are packaged into the payment amount for an item or service and are not separately payable should be excluded from the total number of units of a billing and payment code for a Part B rebatable drug. As stated in the CY 2025 PFS final rule (89 FR 98247), we will remove billing units that are packaged into the payment amount for an item or service and are not separately payable. We codified this policy at § 427.303(b)(3). We have identified rare instances where claims for separate payment have been submitted for a Part B rebatable drug when such claims are payable only as part of a bundled payment. In the CY 2026 PFS proposed rule (90 FR 32635), we clarified that we exclude units associated with such separately billed claims from the rebate calculation consistent with § 427.303(b)(3).

We did not receive public comments on this issue, and we have adopted this clarification.

d. Identification of the Payment Amount Benchmark Quarter (§ 427.302(c))

In the CY 2026 PFS proposed rule (90 FR 32635), we proposed at § 427.302(c)(5) that if data needed to calculate the payment amount in the payment amount benchmark quarter as described in and determined under § 427.302(d)(1) are not available in the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, CMS will use the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code as the payment amount benchmark quarter. Without a payment amount in the payment amount benchmark quarter, we would not be able to calculate Part B inflation rebates for such billing and payment codes. We believe this approach will allow CMS to calculate a payment amount in the payment amount benchmark quarter, incorporating the two-quarter lag used to set payments in alignment with section 1847A of the Act. We made this proposal to address identified instances as described in section III.E.2.e. of this final rule.

This proposal required CMS to make technical edits to and to renumber regulations at § 427.302(c). Therefore, we proposed conforming changes to § 427.302(c) and to redesignate § 427.302(c)(5) as § 427.302(c)(6).

We did not receive public comments on this proposed provision, and we are finalizing as proposed the revisions to § 427.302(c).

e. Identification of the Payment Amount in the Payment Amount Benchmark Quarter (§ 427.302(d)(1))

Section 1847A(i)(3)(C) of the Act specifies use of the "payment amount for the billing and payment code for such drug in the payment amount benchmark quarter" ("payment amount in the payment amount benchmark quarter") in the determination of the inflation-adjusted payment amount. As stated in the CY 2025 PFS final rule (89 FR 98244), to identify the payment amount in the payment amount benchmark quarter, we use the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter. If the published payment limit is not available for the applicable benchmark quarter, we stated we will use the lower of 106 percent of ASP or 106 percent of WAC. However, we have identified instances in which some or all NDCs in a billing and payment code have zero or negative ASP or WAC values. Using such data could result in a payment amount in the payment amount benchmark quarter that is zero, negative, or inappropriately low due to the inclusion of the zero or negative ASP or WAC values. In addition, when the published payment limit is not available, using 106 percent of ASP or 106 percent of WAC to calculate the payment amount in the payment amount benchmark quarter may not be appropriate in instances where the payment limit is based on a different amount, such as in the case of Part B rebatable drugs that are biosimilars for which the add-on amount reflects the payment amount for the reference biological product (as set forth in section 1847A(b)(8) of the Act). For the purposes of calculating a payment amount under the statute, CMS finalized in the CY 2025 PFS final rule (89 FR 97981) that negative or zero manufacturer's ASP data are considered "not available". We also note that the published payment limit for a drug with negative or zero ASP data reported after January 1, 2025, could be based on a positive amount that is carried forward from a previous quarter in accordance with § 414.904(i).

In the CY 2026 PFS proposed rule (90 FR 32636), we proposed to remove from § 427.302(d)(1) "determined under section 1847A of the Act". This text was inadvertently included in the CY 2025 PFS

final rule (89 FR 98583) and needs to be removed because the statutory provision governing the payment amount in the payment amount benchmark quarter, section 1847A(i)(3)(C)(i) of the Act, does not limit that amount to payment amounts determined under section 1847A of the Act and because the payment limits for some Part B rebatable drugs are not determined under section 1847A of the Act.

Additionally, we proposed to revise § 427.302(d)(1)(i) by removing "If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS will use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC" (90 FR 32636). We also proposed to revise § 427.302(d)(1)(ii) by removing "If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS will use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of this section, CMS will consider to be the payment amount for the payment amount benchmark quarter." If a published payment limit is not available for the applicable payment amount benchmark quarter, at § 427.302(d)(1)(i), we proposed to calculate the payment amount in the payment amount benchmark quarter using positive ASP or positive WAC data reported by manufacturers to the ASP Data Collection System.[351] Additionally, at § 427.302(d)(1)(ii), if neither positive ASP nor positive WAC data are available in the ASP Data Collection System for the given quarter, we proposed to use WAC data from other public sources for the given quarter to calculate the payment amount in the payment amount benchmark quarter. We believe these proposals would allow CMS to calculate a payment amount in the payment amount benchmark quarter that aligns with section 1847A of the Act, rather than strictly limiting this calculation to the lower of 106 percent of ASP or 106 percent of WAC as reported for a given drug, as previously stated in the CY 2025 PFS final rule (89 FR 98244), which may not align with CMS' policy for calculating payment limits under § 414.904. Under this proposed approach, we would also avoid calculating inappropriately large inflation rebate amounts for drugs that had zero or negative sales in their payment amount benchmark quarter.

We did not receive public comments on this proposed provision, and we are finalizing as proposed the revisions at § 427.302(d)(1).

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[351] Available at https://portal.cms.gov/portal/.

f. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 427.500 through 427.505)

Section 1847A(i)(1)(A) of the Act requires the Secretary to provide a report to each manufacturer of a Part B rebatable drug with the following information not later than 6 months after the end of an applicable calendar quarter: (1) the total number of billing units for each Part B rebatable drug; (2) the amount, if any, of the excess average sales price increase (the amount by which the specified amount exceeds the inflation-adjusted payment amount as calculated at § 427.302(g)) for an applicable calendar quarter; and (3) the rebate amount for the Part B rebatable drug. In compliance with section 1847A(i)(1)(B) of the Act, manufacturers of a Part B rebatable drug must provide a rebate for each Part B rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1847A(i)(1)(A) of the Act.

As we explained in the CY 2026 PFS proposed rule (90 FR 32636), in accordance with §§ 427.504 and 427.505, CMS has established a standard method and process to issue Rebate Reports to manufacturers of Part B rebatable drugs and to accept manufacturer rebate payments. CMS has established an Online portal, the "Manufacturer Payment Portal" (MPP),[352] administered by a CMS contractor, through which manufacturers will access their Rebate Reports, submit Suggestions of Error, as applicable, and pay rebate amounts due, as described at §§ 427.504 and 427.505. Manufacturers of Part B rebatable drugs should provide points of contact to view the rebate reports described at §§ 427.501 and 427.502, enter and modify banking information, and initiate payment of rebate amounts through the MPP.

We did not make any proposals associated with the method and process to issue Rebate Reports to manufacturers of Part B rebatable drugs and to accept manufacturer rebate payments in the CY 2026 PFS proposed rule. We did not receive public comments on these policies.

i. Rebate Reports and Reconciliation (§ 427.501)

As stated in the CY 2025 PFS final rule (89 FR 98264), we codified a multistep process to provide a manufacturer, as defined at § 427.20, with the rebate information specified in section 1847A(i)(1)(A) of the Act. Specifically, in the CY 2025 PFS final rule (89 FR 98264), CMS established the information that will be included in a Rebate Report at § 427.501, including the NDC(s) and billing

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[352] See: *https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-onboarding-memo.pdf.*

and payment codes identified for the Part B rebatable drug, the total number of billing units, the applicable calendar quarter, and the rebate amount due, among other items specified at § 427.501. Consistent with the approach specified in section 80.3 of the Medicare Part B Drug Inflation Rebate Guidance, published December 14, 2023, we proposed in the CY 2026 PFS proposed rule to add paragraph (c)(3) at § 427.501 to clarify that CMS would report the manufacturer's rebate amount due as a dollar amount that is rounded to the nearest cent (90 FR 32636). CMS did not specify an approach to reporting of the rebate amount in the CY 2025 PFS final rule and we believe it is necessary to provide this information to manufacturers to provide notice of CMS' approach to rounding of the rebate amount. The calculation steps specified in subpart D of part 427 will not include rounded values.

We did not receive public comments on this proposed provision to add paragraph (c)(3) in § 427.501, and we are finalizing as proposed at § 427.501(c)(3).

In the CY 2025 PFS final rule (89 FR 98265), to determine which data elements would be included when CMS reports the rebate amount to the manufacturer, we stated that we considered the statutory requirements outlined in section 1847A(i)(1)(A)(i) through (iii) of the Act to determine what information is necessary for manufacturers to review the accuracy of the rebate amount while also protecting proprietary information. As stated on page 98578 of the CY 2025 PFS final rule, CMS structured a two-step reporting process to first include a Preliminary Rebate Report to provide an initial notice to manufacturers regarding whether they may owe a rebate amount, followed by the Rebate Report. Further, we proposed and finalized additional data elements within the Preliminary Rebate Reports and the Rebate Reports not listed in statute based on input from public comments (for example, the applicable benchmark period, the rebate period CPI-U). CMS did not finalize additional elements suggested, such as claims-level data, after weighing whether any such additional information fulfilled CMS' statutory obligation and the potential benefits to manufacturers against the administrative burden additional reporting would impose on the agency and operational feasibility. The data elements set forth in § 427.501(b)(1) and (c)(1) satisfy these considerations.

In the CY 2026 PFS proposed rule, CMS clarified that certain data elements provided to manufacturers in Preliminary Rebate Reports, Rebate Reports, and reconciled reports of a rebate amount (which may each include the same elements, revised as applicable due to updates in the data), are

provided to manufacturers of a Part B rebatable drug in a manner consistent with sections 1927(b)(3)(D) and 1847A(f)(2)(D) of the Act. Section 1927(b)(3)(D) of the Act specifies that information disclosed by manufacturers or wholesalers under section 1927(b)(3) (submissions of drug product and pricing information under the National Drug Rebate Agreement (NDRA)) or under a Master Agreement with the Secretary of Veterans Affairs (other than WAC) is confidential and shall not be disclosed by the Secretary in a way that discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except as otherwise allowed in section 1927(b)(2)(D)(i) through (vii) of the Act. Section 1927(b)(3)(D)(i) of the Act provides an exception to this confidentiality requirement as the Secretary determines to be necessary to carry out certain sections of the Act, including section 1847A of the Act (that is, the Part B Drug Inflation Rebate Program). Section 1847A(f)(2)(D) of the Act contains parallel confidentiality protections for ASP information reported by manufacturers and wholesalers, including a parallel exception for purposes of Part B rebate effectuation, and would apply to ASP data reported by entities that do not have a NDRA and that report ASP data outside the MDRP.

Specifically, CMS anticipates that most data included in Preliminary Rebate Reports, Rebate Reports, reconciled Preliminary Rebate Reports, and reconciled Rebate Reports will not implicate sections 1927(b)(3)(D) or 1847A(f)(2)(D) of the Act, as CMS anticipates that in most cases the party that will receive these reports will be the same party that reported the relevant information. However, CMS acknowledges that some situations may raise a possibility of disclosure by the Secretary of AMP or ASP information, or information derived therefrom, to a party besides the party that reported the information originally; such situations could implicate section 1927(b)(3)(D) and/or section 1847A(f)(2)(D) of the Act. Such situations may include, but are not necessarily limited to: (1) transfer of a rebatable drug from one manufacturer to another manufacturer, such that the manufacturer identified in the Rebate Report differs from the manufacturer that originally reported certain benchmark pricing information; and (2) cases in which CMS displays a specified amount, the total HCPCS units, and the proportion of manufacturer-reported ASP units for reports associated with grouped HCPCS codes. In instances where the parties may be different, CMS emphasizes that the data included in a report of the rebate amount is based on CMS' independently performed calculations. Although these calculations rely on information disclosed by manufacturers as inputs, in most cases the data reported in a Preliminary Rebate Report and

a Rebate Report (or a reconciled version of these reports) will not be identical to the information reported by manufacturers (for example, manufacturers report ASP data at the NDC-11 level, whereas the payment amount in the payment amount benchmark quarter reflects an aggregated, HCPCS-level value that was calculated using the NDC-11-level ASP data). Therefore, reporting such data elements to another manufacturer for purposes of the Medicare Part B Drug Inflation Rebate Program would not violate the confidentiality requirements in sections 1927 and 1847A of the Act.

Second, in the CY 2025 PFS final rule (89 FR 98266), CMS stated that the purpose of providing additional data elements not explicitly listed in sections 1847A(i)(1)(A)(i) through (iii) of the Act (for example, the payment amount in the payment amount benchmark quarter, specified amounts, and certain unit data) is based on CMS' assessment of "data elements are necessary [for a manufacturer] to review the Preliminary Report for a Suggestion of Error." Providing these data in the Preliminary Rebate Report (and corresponding subsequent reports) ensures that: (1) manufacturers will be able to submit a Suggestion of Error, thereby promoting accuracy in the implementation of the rebate program; and (2) manufacturers will have advanced notice of a potential rebate amount due. Section 1847A(i)(1)(A)(i) of the Act specifies that for each Part B rebatable drug, the Secretary shall report to each manufacturer information on the total number of units of the billing and payment code. However, this level of information alone is not sufficient to support CMS' goal of providing enough information for a manufacturer to submit a Suggestion of Error, if necessary. For Part B rebatable drugs, it is necessary to provide the proportion of ASP-reported units in addition to providing the total HCPCS units (as required by statute) so that the manufacturer has sufficient information to understand the total rebate amount calculated. We acknowledge that by providing the proportion of ASP-reported units, a manufacturer could estimate the proportion of ASP-reported units for another drug(s) included in the same HCPCS code. However, we believe that providing this information is necessary to carry out the rebate program because it enables manufacturers to submit a potential Suggestion of Error, which promotes accuracy in the calculation of the rebate amount.

We did not make any proposals associated with the data elements provided to manufacturers of Part B rebatable drugs in Preliminary Rebate Reports, Rebate Reports, and reconciled reports of a rebate amount in the CY 2026 PFS proposed rule. We did not receive public comments on these policies.

ii. Rebate Report for Applicable Calendar Quarters in CY 2023 and CY 2024 (§ 427.502)

As stated in the CY 2025 PFS final rule (89 FR 98271), we codified at § 427.502 the option afforded to CMS in section 1847A(i)(1)(C) of the Act to delay sending the information required by section 1847A(i)(1)(A) of the Act for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025. Specifically, per § 427.502, CMS issued one report for the 4 applicable calendar quarters in CY 2023 and one report for the 4 applicable calendar quarters in CY 2024. Additionally, CMS will send a reconciled rebate amount for the four applicable calendar quarters in CY 2024 9 months after the Rebate Report, to allow for 12 months of claims run-out for each applicable calendar quarter. We stated in the CY 2025 PFS proposed rule (89 FR 61959) that this approach aligns claims and payment data run-out with the run-out used during a regular reconciliation cycle. However, CMS finalized the regulatory text specifying the time periods for regular reconciliation cycles at § 427.501(d) with text that provides CMS with operational flexibility as to the exact date the report with the reconciled rebate amount will be provided to each manufacturer of a Part B rebatable drug by including the word "within" prior to the specified date. In the CY 2026 PFS proposed rule (90 FR 32637), we proposed to amend § 427.502(c)(2)(ii) to add the word "within" prior to "nine months" to be consistent with the regulatory text and cadence for regular reconciliation cycles as well as to provide operational flexibility on the timing of the release of the report with the reconciled rebate amount.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.502(c)(2)(ii).

3. Medicare Part D Drug Rebates for Certain Drugs and Biologicals with Prices that Increase Faster than the Rate of Inflation

a. Clarification Regarding the Payment Amount Benchmark Period for Certain Subsequently Approved Drugs

In the CY 2025 PFS final rule (89 FR 98280), CMS finalized policies to identify the payment amount benchmark period as set forth in § 428.202(c). At § 428.202(c)(2), we finalized that for a subsequently approved drug, the payment amount benchmark period is the first calendar year beginning after the drug's first marketed date. At § 428.202(c)(4), we finalized that, notwithstanding § 428.202(c)(2), for a subsequently approved drug for which there are no quarters during the first calendar

year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act for the NDC-9, including information as set forth in § 428.202(d)(3), the payment amount benchmark period is the first calendar year in which such NDC-9 has at least 1 quarter of AMP reported.

At § 428.202(c)(3), we specified that the payment amount benchmark period must be no earlier than calendar year 2021 for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act for the NDC-9, including information as set forth in § 428.202(d)(3). At the time of development for rulemaking on the CY 2025 PFS, we did not believe it was necessary to clarify at § 428.202(c)(2) or (c)(4) that the payment amount benchmark period for a subsequently approved drug also must be no earlier than calendar year 2021, since a subsequently approved drug is by definition a Part D rebatable drug first approved or licensed by the FDA after October 1, 2021.

However, we have identified rare instances in which a subsequently approved drug's first marketed date precedes the FDA approval date reported under section 1927(b)(3)(A)(v) of the Act. It is therefore possible that a subsequently approved drug could have a first marketed date prior to 2020; in other words, the first calendar year beginning after the drug's first marketed date could precede 2021. The definition of the payment amount benchmark period at section 1860D-14B(g)(3) of the Act and the description of a subsequently approved drug at section 1860D-14B(b)(5)(A) of the Act suggest that a Part D rebatable drug should not have a payment amount benchmark period prior to 2021. As such, in the CY 2026 PFS proposed rule (90 FR 32638), we proposed to clarify that the payment amount benchmark period identified at § 428.202(c)(1) through (c)(5) for a Part D rebatable drug will be no earlier than 2021 in all instances. We also proposed to clarify that the payment amount benchmark period set forth at § 428.202(c)(3) or (c)(4) cannot precede the payment amount benchmark period set forth at § 428.202(c)(1) or (c)(2), as applicable, for a Part D rebatable drug.

We did not receive public comments on this issue, and we have adopted this clarification.

b. Clarification Regarding Calculation of the Benchmark Period Manufacturer Price or AnMP in Instances of Quarters with Monthly Units but no Quarterly AMP

In the CY 2025 PFS final rule (89 FR 98287), CMS established policies for calculating the benchmark period manufacturer price and AnMP, as applicable, in situations in which certain data are missing but CMS still has sufficient data to complete the calculations. At § 428.202(g)(1), we finalized that if there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units.

In the CY 2026 PFS proposed rule (90 FR 32638), we clarified that we are taking the same approach for the inverse scenario. That is, if there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act but has reported units under section 1927(b)(3)(A)(iv) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with AMP. In other words, when a manufacturer has not reported AMP for a quarter but has reported units for months in that quarter, CMS will not use the units from that quarter in the calculation of the benchmark period manufacturer price or AnMP, as applicable. To the extent that a manufacturer reports a quarterly AMP value of zero for a given quarter, CMS will not consider zero to be a valid value and will instead consider AMP to be missing for that quarter.[353]

We will monitor this approach and may modify our policy in the future. We also remind manufacturers of their reporting obligations under section 1927(b) of the Act and § 447.510 of this title and that failure to provide timely information required under those authorities may result in penalties as detailed in section 1927(b)(3)(C)(i) of the Act.

We did not receive public comments on this issue, and we have adopted this clarification.

c. Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements (§ 428.203(b)(2))

Section 1860D-14B(b)(1)(B) of the Act requires that beginning with the plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, for an applicable period, those

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[353] See CMS instructions for reporting AMP when a zero or negative value occurs. For example: *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-038.pdf* and *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf.*

units for which a manufacturer provided a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units will only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026.

As we stated in the CY 2025 PFS final rule (89 FR 98289), data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D-14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and we do not currently have access to this data through other means. We understand that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale, and that 340B covered entities (hereinafter "covered entities") typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based solely on Part D claims submitted to CMS by the covered entity. For these reasons, in the CY 2026 PFS proposed rule (90 FR 32639), we proposed a claims-based methodology to exclude 340B units starting on January 1, 2026. Additionally, we proposed establishing a voluntary 340B repository for data from covered entities about 340B units that we anticipate will allow for CMS to identify 340B units at the claim level in future applicable periods (*see* 90 FR 32641).

i. Summary of Policies Discussed in the CY 2025 PFS Final Rule

In the CY 2025 PFS proposed rule (89 FR 62245), to fulfill the statutory requirement to remove 340B units from rebate calculations beginning on January 1, 2026, we proposed at § 428.203(b)(2)(i) to exclude from the total number of units determined under §428.203(a), units for which a manufacturer provided a discount under the 340B Program ("340B units"). At § 428.203(b)(2)(ii), we proposed to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period.

In the CY 2025 PFS proposed rule (89 FR 61971), CMS also solicited comments on a Medicare Part D Claims Data 340B Repository (hereinafter, "340B repository"). This approach would require that

covered entities submit certain data elements from Part D 340B claims to the 340B repository on a retrospective basis. In response to this comment solicitation, many commenters expressed strong support for a 340B repository.

In the CY 2025 PFS final rule (89 FR 98593), CMS finalized the proposal at § 428.203(b)(2)(i) to exclude from the total number of units determined under § 428.203(a) units for which a manufacturer provided a discount under the 340B Program ("340B units"), as well as the proposal at § 428.203(b)(2)(ii) to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. CMS stated that it would explore avenues to implement section 1860D-14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provided a discount under the 340B Program starting January 1, 2026, through the establishment of a 340B repository.

In the CY 2026 PFS proposed rule, CMS did not repropose the estimation methodology proposed in the CY 2025 PFS proposed rule but did consider this estimation percentage as an alternative to the proposal in the CY 2026 PFS proposed rule, as described in section III.E.3.c.iii. of the CY 2026 PFS proposed rule titled "Alternative Policy Considered" (*see* 90 FR 32641). Rather, we proposed to implement § 428.203(b)(2) using a claims-based methodology to remove 340B units beginning January 1, 2026 (*see* 90 FR 32639). We also proposed to establish a Part D claims data 340B repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying 340B units for removal in a future applicable period (*see* 90 FR 32642).

We received public comments that broadly addressed the 340B Program and our proposed approach to implement § 428.203(b)(2) using a claims-based methodology and to establish a 340B repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying 340B units for removal in a future applicable period. The following is a summary of these general comments we received and our responses.

Comment: Some commenters raised the topic of burden associated with the proposed 340B units identification methodologies. A few commenters requested that the methodologies undergo pilot testing

prior to use and any burden from these processes should not be shifted to prescribers or pharmacies. A few commenters suggested a thoughtful implementation to ensure added administrative burden from 340B identification processes does not impede access for 340B hospitals.

Response: We appreciate the commenters' feedback. The proposed claims-based methodology does not require covered entities to provide information to CMS, as information needed for this approach is obtained from claims data and other existing data sources. The repository will begin accepting voluntary data submissions in 2026. The agency intends to utilize its experience receiving and assessing voluntary submissions to the repository beginning in 2026 to, among other things, refine its information collection practices to reduce any additional burden on covered entities associated with submissions to the repository.

Comment: A commenter expressed the opinion that the proposed methodologies do not go far enough to ensure the 340B Program functions as intended and does not prevent duplicate discounts between the 340B program and such programs as the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program. Another commenter commended the proposed methodologies as progress over prior years' proposals but stated that they still fail to adequately address the issue of duplicate discounts across Federal programs and present a patchwork attempt to address 340B duplicate discounts across different programs.

Response: We appreciate the commenters' suggestions. The claims-based methodology proposed in the CY 2026 PFS proposed rule for identification of 340B units is exclusively for use in the Medicare Part D Drug Inflation Rebate Program to implement the statutory requirement at section 1860D-14B(b)(1)(B) of the Act to exclude from the calculation of Part D inflation rebates units for which a manufacturer provided a discount under the 340B Program. As previously discussed, the 340B repository is intended to, among other things, provide CMS with experience with which it will refine its information collection practices. We will evaluate the effectiveness of the proposed claims-based methodology, finalized herein, in identifying 340B units for exclusion from Part D inflation rebate calculations. The general function of the 340B Program and duplicate discounts among programs outside of the Part D Drug Inflation Rebate program is outside of the scope of this final rule.

Comment: A commenter requested that CMS extend the timeline for implementing the proposed 340B unit identification from January 1, 2026, to provide smaller manufacturers with more time for budgetary planning, legal review, and functional adjustments to operationalize any changes. A commenter encouraged the delay of 340B unit identification for the Medicare Part D Drug Inflation Rebate Program due to the added burden on 340B hospitals from the HRSA 340B Rebate Model Pilot Program beginning next year.

Response: We appreciate the commenters' feedback. Section 1860D-14B(b)(1)(B) of the Act requires that beginning with the plan year 2026, we must exclude from the total number of units for a Part D rebatable drug, for an applicable period, those units for which a manufacturer provided a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins in October 2025, we will exclude the 340B units starting on January 1, 2026.

Comment: A few commenters expressed broad concerns about any proposal that would overestimate 340B units, with a commenter expressing their belief that both the claims-based methodology and the 340B repository would overestimate 340B units, and another commenter stating that any methodology that overestimates 340B use could result in loss of resources that would harm patients who depend on the 340B Program. A commenter recommended CMS collaborate with 340B interested parties to develop more accurate and less burdensome methods but did not specify to which proposal they referred.

Response: We appreciate the commenters' feedback. We note that neither details regarding which methodology would overestimate 340B units, nor how such methodology would overestimate units, were provided by the commenters. If concerns were related to overestimation in the claims-based methodology, we refer readers to the comment summaries and our responses below on this topic. If the concerns were related to overestimation in the 340B repository, we remind readers that the 340B repository will be used to begin testing the usability of data voluntarily submitted by covered entities and will not be used to remove 340B units from Part D inflation rebate calculations at this time. We will take commenters' views on overestimation into account when evaluating the usability of 340B repository data. With regards to the comment expressing concern with a potential loss of resources due to overestimation of 340B units, we note that nothing in the claims-based methodology nor the 340B repository would

affect the resources allocated to covered entities since neither affects the determination of 340B eligibility of claims.

With regard to the comment addressing accuracy and burden, the commenter did not provide specifics on their concerns or to which proposal they referred. However, we note that the claims-based methodology, which is the methodology that CMS will use to remove 340B units from Part D inflation rebate calculations beginning January 1, 2026, is a comprehensive analytic approach that has undergone rigorous testing and refinements, as described later in this section, and that makes use of the best data sources available to CMS at this time. Therefore, we believe that the claims-based methodology is appropriate and sufficient to implement section 1860D-14B(b)(1)(B) of the Act and § 428.203(b)(2). Additionally, the claims-based methodology does not impose any burden on covered entities or manufacturers. For summaries of comments received on burden as it relates to the repository, we refer readers to the discussions in the Collection of Information Requirements section of this final rule, which highlights CMS' interest in and efforts to reduce any burden associated with voluntary submissions to the 340B repository.

ii. Claims-Based Methodology to Remove 340B Units from Rebate Calculations

In the CY 2026 PFS proposed rule, we proposed to implement § 428.203(b)(2) using a claims-based methodology[354] to remove 340B units from the Part D inflation rebate calculations by evaluating whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE record as a 340B contract pharmacy (hereinafter "Prescriber-Pharmacy Methodology"). *See* 90 FR 32639.

As proposed, for the Prescriber-Pharmacy Methodology, once a PDE record is identified as potentially 340B-eligible, the units associated with that PDE record would be removed from the rebate calculation, that is, the units associated with that PDE record would be considered "340B units" and excluded from rebate calculations in implementing § 428.203(b)(2). We understand that the determination

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[354] The 340B claims-based methodology described herein uses elements of the 340B simulation described in the published work: Nikpay, S., Bruno, J. P., & Carey, C. (2024). Recent court ruling could increase the size and administrative complexity of the 340B Program. *Health affairs scholar*, *2*(12), qxae157. *https://doi.org/10.1093/haschl/qxae157*.

of potential 340B-eligibility of a PDE record using the methodology described herein does not necessarily mean that the covered entity replenished (or can in the future replenish) the units at the 340B price, and we therefore believe the proposed claims-based methodology may overestimate the number of units that are units for which a manufacturer provided a discount under the 340B Program. Examples of PDE records that would be identified as being potentially 340B-eligible by the claims-based methodology, but for which the covered entity may not be able to make a corresponding purchase of the accumulated units at the 340B price, include those for which: (1) a drug manufacturer placed restrictions on the 340B contract pharmacy (hereinafter "contract pharmacy") that resulted in a non-340B price; (2) the NDC dispensed on the claim was discontinued, in shortage, or generally unavailable from the pharmaceutical wholesaler; (3) the covered entity did not accumulate enough units to replenish a full bottle of the drug; or (4) the prescription was subsequent to care provided outside of a covered entity. The approach described in this section would identify PDE records as potentially 340B-eligible based on two criteria: (1) the prescriber with the NPI listed on the PDE record provides care at a covered entity, and (2) the pharmacy NPI on the PDE record is a contract pharmacy for that same covered entity.

To establish a list of providers considered to be 340B-affiliated providers, we proposed to first create a list of prescriber NPIs from PDE records with dates of service within each applicable period. This file would be generated at the prescriber-month level and capture prescriber NPIs with active billing histories for specific months within the applicable period. CMS would then crosswalk this list of prescriber NPIs and months to the provider fields[355] on Medicare Fee-For-Service (FFS) Part A inpatient claims and Part B outpatient claims and professional claims to identify the Medicare Provider Numbers (MPNs)[356] through which each prescriber NPI billed for each month that they were active in the PDE data. The resulting file would include prescriber NPI, MPN, and month combinations within the applicable period. We then proposed to filter the collated list of prescriber NPI and MPN combinations using the 340B Office of Pharmacy Affairs Information System (OPAIS) database,[357] which records the available MPNs for

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[355] Provider field types include billing, rendering, attending, operating, other, and referring.

[356] There exist inconsistencies between how MPN is described in the 340B OPAIS database and the 2007 CMS System Manual, which states "In order to avoid confusion with the NPI, the Medicare/Medicaid Provider Number (also known as the OSCAR Provider Number, Medicare Identification Number or Provider Number) has been renamed the CMS Certification Number (CCN)." For the purpose of this discussion, CMS uses MPN interchangeably with CCN.
See: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r29soma.pdf.*

[357] See: *https://340bopais.hrsa.gov/home.*

covered entities that are actively participating in the 340B Program during the applicable period. Each prescriber NPI affiliated with an MPN that was also an active covered entity listed on the OPAIS database for that particular month would be considered a 340B-affiliated prescriber for the month within the applicable period.

CMS acknowledges that the 340B OPAIS database may not list all pharmacies that dispense 340B-eligible drugs, including covered entities that have "in-house" pharmacies that are not registered in the 340B OPAIS database and 340B-eligible State and territorial Aids Drug Assistance Programs (ADAPs) that access 340B prices through rebates after their purchase of the drug instead of receiving the discounted price at the time of purchase from a contract pharmacy registered in the 340B OPAIS database. We solicited comments on whether and how to account for this limitation in the identification of 340B dispenses in the Prescriber-Pharmacy Methodology. We received public comments on this comment solicitation. A summary of the comments we received, and our responses are included below. In addition, we acknowledge that not all covered entities have an MPN or report their MPN in the 340B OPAIS database, which may result in an inability for CMS to designate claims affiliated with such covered entities as being potentially 340B-eligible using this methodology. Notably, we understand that hospitals are required to report their MPN in the 340B OPAIS database if they intend to use 340B drugs for their Medicaid patients,[358] and that hospitals make up the significant majority of 340B volume. To address the missing MPN scenarios, CMS solicited comments on a methodology to augment the prescriber NPI and MPN file described previously in this final rule by using NPI when the NPI is listed in the 340B OPAIS database, but MPN is not. We would use data sources such as CMS' Integrated Data Repository to map 340B OPAIS provided organizational NPIs to corresponding individual NPIs and MPN, when possible, to establish a supplemental list of prescriber NPIs that are associated with covered entities. Each prescriber NPI that is determined to be associated with a covered entity NPI, as listed in the 340B OPAIS database, would be considered a 340B-affiliated prescriber for the month within the applicable period. We solicited comments on the benefits of using this augmented 340B-affiliated prescriber NPI approach to address covered entities that do not have MPN's listed in the 340B OPAIS database that will help to ensure a broader possible combination of prescriber-covered entity pairings than using the covered entity's

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[358] See: *https://www.hrsa.gov/opa/registration*.

organizational NPI from the 340B OPAIS database alone, as well as alternative methods to consider for how CMS could address the described scenario.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for CMS' proposal to augment the prescriber NPI and MPN file by using NPI when the NPI is listed in the 340B OPAIS database but an MPN is not. A few of these commenters supported this method because they believed it would result in a more accurate methodology, and another of these commenters stated that this approach appropriately handles situations where a covered entity does not have an MPN. A commenter requested that CMS clarify how it plans to account for the fact that the OPAIS database does not include MPNs for every covered entity. A few commenters raised the concern that using the MPN to identify covered entities or providers affiliated with them would be insufficient without additional, robust, and reliable NPI mapping for each organization.

Response: We appreciate the commenters' suggestions, and we understand that the association of MPN to the provider does not always correctly categorize the affiliated relationship between the provider and the covered entity. We believe that cross-walking NPI to MPN is a necessary step in utilizing publicly available information to establish a list of 340B providers, which is an essential element to provide a transparent Prescriber-Pharmacy Methodology. There does not exist a public account of providers affiliated with covered entities, either through employment at covered entities or through provision of contracted services on behalf of covered entities.

After consideration of public comments, we are adopting the proposal with modifications described herein. Specifically, to address the limitation raised by commenters regarding the use of MPNs to identify covered entities and providers affiliated with them, CMS will additionally engage in mapping 340B OPAIS-provided organizational NPIs to corresponding individual NPIs and MPNs using data sources such as the CMS Integrated Data Repository to establish a supplemental list of prescriber NPIs associated with covered entities. The resulting augmented 340B-affiliated prescriber NPI file will help to ensure a broader possible combination of prescriber-covered entity pairings than using the covered entity's organizational NPI from the 340B OPAIS database alone. Additional modifications to enhance the accuracy and completeness of the claims-based methodology are described later in this rule.

Next, we proposed to use the 340B OPAIS database to identify registered contract pharmacies that have an active agreement with a covered entity in the 340B OPAIS database during months within the applicable period and develop a list of contract pharmacy names, addresses, and active months for each associated covered entity. We would then merge pharmacy NPIs onto this file using the name and address fields reported to the National Council for Prescription Drug Programs (NCPDP). We understand that matching the list of contract pharmacy names and addresses to the NCPDP database will not rely on the use of a single discrete data field and may require CMS to utilize a methodology that includes: (1) cleaning addresses to account for variations in spelling, abbreviations, punctuations, etc. between the pharmacy names and addresses from both sources; (2) geocode matching between the pharmacy addresses contained in each source; and (3) fuzzy string matching on pharmacy name and address fields after cleaning these fields. Specifically, CMS may conduct a cartesian join to generate potential matches between pharmacies from each data source located in the same State, limit these potential matches to pharmacies estimated to be within 0.2 miles of one another,[359] and select a final match for each 340B OPAIS pharmacy based on fuzzy string matching between the pharmacy name and address fields in each database.[360] We proposed to use a targeted analysis to conduct a manual review of this matching algorithm to identify and correct errors or omissions. CMS acknowledged that this matching algorithm may result in an inability to associate a small percentage of contract pharmacies with NPIs.

The output of the two preceding processes would be: (1) a month-level file containing 340B-affiliated prescriber NPIs and their associated MPNs and/or organizational NPIs, and (2) a month-level file containing pharmacy NPIs for contract pharmacies of covered entities and the MPNs or organizational NPIs of these covered entities. CMS would join these two files by MPN or organizational NPIs and month to create a month-level file containing 340B-affiliated prescriber NPIs and pharmacy NPIs for contract pharmacies associated with these covered entities. Based on preliminary analyses of this claims-based methodology, for most Part D drugs, CMS stated that we expect to remove about 10 percent to 35 percent of

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[359] The 0.2 mile threshold was previously adopted in Nikpay, S., Bruno, J. P., & Carey, C. (2024). Recent court ruling could increase the size and administrative complexity of the 340B Program. *Health affairs scholar*, *2*(12), qxae157. *https://doi.org/10.1093/haschl/qxae157.*

[360] CMS proposed to use a fuzzy-matching approach that matches the similarity between the names and addresses. This approach first counts the characters that match. Next, it examines how close those characters are, accounting for transpositions in each name or address. Accounting for transpositions addresses common typing mistakes such as entering the right characters in the wrong order.

the total number of units[361] determined under § 428.203(a) used to calculate the total rebate amount determined under § 428.201(a). We emphasized that this approximation is preliminary and may vary significantly across different Part D rebatable drugs.

We noted that a prescriber NPI may have multiple affiliated covered entities, and that a covered entity may have multiple contract pharmacies. Using this set of prescriber and pharmacy pairings, CMS would identify PDE records during the applicable period that have prescriber ID, service provider ID, and claim date fields that match one of the paired combinations of 340B-affiliated prescriber NPI, pharmacy NPI, and month. For PDE records that match against these pairings, the units associated with those PDE records would be considered 340B units and would be removed from the total number of units dispensed under Part D (as determined under § 428.203) used to calculate the total rebate amount.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for CMS' proposed claims-based methodology. A commenter believed that the proposed methodology strikes an appropriate balance between accuracy and reducing the reporting burden on providers and Part D plans. Another commenter supported CMS' claims-based Prescriber-Pharmacy Methodology to exclude 340B acquired units from calculations of Part D inflation rebates, as they believed that the proposed 340B repository had the potential to place additional burdens on covered entities, which they opposed. Some commenters viewed the proposed Prescriber-Pharmacy Methodology as an improvement over the estimation approach proposed in the CY 2025 PFS proposed rule. A commenter appreciated that the proposed Prescriber-Pharmacy Methodology is more granular than the estimation methodology proposed in the previous CY 2025 PFS proposed rule and acknowledged CMS attempts to improve upon last year's approach. A commenter believed that the proposed Prescriber-Pharmacy Methodology was better suited to meet the statutory obligation and less administratively burdensome than the proposed 340B repository. A few commenters expressed support for putting forth a proposal that did not require pharmacies to include a 340B claim indicator at the point of sale.

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[361] The preliminary analysis does not take into account any additional methods discussed that would further augment the claims-based methodology for covered entities that do not have MPN's listed in the 340B OPAIS database.

Response: We appreciate the commenters' support of CMS' proposed policies for the removal of 340B units from Part D inflation rebate calculations using the proposed claims-based methodology. As outlined in this final rule, We are adopting the proposal for the Prescriber-Pharmacy Methodology to determine the total number of units of a Part D rebatable drug which will be considered "340B units" and excluded when calculating a Part D inflation rebate as described at § 428.203(b)(2) in order to implement section 1860D-14B(b)(1)(B) of the Act.

Comment: Many commenters raised concerns related to the proposed claims-based methodology outlined in the CY 2026 PFS proposed rule. Many commenters recommended that CMS reconsider a refined version of the proposed estimation methodology from the CY 2025 PFS proposed rule, believing that the claims-based methodology outlined in the CY 2026 PFS proposed rule was a less accurate alternative. While many commenters recognized CMS' efforts to develop an approach to address the removal of 340B units in the inflation rebate calculation, and CMS' efforts to be responsive to prior feedback on proposed methodologies, these commenters believed that CMS should reconsider any methodology that estimates or approximates 340B units and should instead develop a more accurate accounting of 340B claims data to calculate the appropriate number of units of a Part D rebatable drug for which a discount was provided under the 340B Program for the applicable period that begins on October 1, 2025. Some commenters stated that any estimation methodology could be considered imprecise and likely would not provide a complete accounting of all Part D 340B claims. A few commenters believed that the proposed approach was inconsistent with statutory requirements in section 1860D-14B(b)(1)(B) of the Act and that any methodology that does not accurately identify every eligible 340B unit does not align with Congress's mandate. Many commenters highlighted areas that they believed were limitations of the proposed claims-based estimation methodology. In addition to the limitations described in the CY 2026 PFS proposed rule, commenters noted concerns with the accuracy of the methodology, the potential for some 340B discounts provided to covered entities to not be identified by the methodology, the burden that will be taken on by the agency to implement such a methodology, and the cost and lack of transparency in the calculated 340B units to remove from the rebate calculation. Some commenters requested that CMS require the use of 340B and non-340B claims indicators appended to submitted Part D claims to more accurately identify 340B claims. Additionally, some commenters requested that CMS expedite the implementation of

the repository instead of pursuing the proposed claims-based methodology. A few commenters requested that CMS only use a methodology that approximates the number of 340B claims for as short a period as possible and stated their belief that moving toward a repository or solution that ensures accurate identification and exclusion of 340B claims is the best, most accurate path. A commenter stated that the proposed claims-based methodology to remove 340B units from the inflation rebate calculation contradicts the expectations CMS has for manufacturers to comply with statutory requirements specified at section 1193(d)(2) of the Act to provide the maximum fair price to dispensing entities in a nonduplicated manner with the 340B ceiling price. Specifically, the commenter stated CMS policy in Medicare Drug Price Negotiation Program guidance states that the NPI alone is insufficient to determine 340B eligibility.

Response: As outlined in the CY 2025 PFS final rule (89 FR 98291), after considering the data limitations of the proposed estimation methodology and public comments that highlighted related concerns and limitations of this approach, we did not finalize the proposed estimation methodology for the applicable period beginning on October 1, 2025. We would like to reiterate that, as we stated in the CY 2025 PFS final rule (89 FR 98289), data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D-14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and we do not currently have access to this data through other means. We believe the Prescriber-Pharmacy Methodology is appropriate, transparent, and consistent with CMS' authority under sections 1860D-14B(b)(1)(B), 1102(a), and 1871(a)(1) of the Act, the latter of which provides the authority to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program. We intend to use the described methodology unless and until a different method to remove 340B units is proposed and finalized. As stated in the CY 2025 PFS proposed rule (89 FR 61972), we understand that the dispensing entity may not know the 340B status of a Part D drug at the point of sale and that covered entities may identify the 340B status of a Part D drug retrospectively. Therefore, we believe there may be more reliable and/or less burdensome ways to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D than requiring a 340B indicator to be included on the PDE record. Additionally, we do not believe a claims indicator is needed to report covered Part D drugs or biological products that were not purchased under the 340B Program.

Regarding the comment related to the comparison of policies set forth in the Medicare Drug Price Negotiation Program and Medicare Part D Drug Inflation Rebate Program with regard to use of NPI as confirmation of a Part D claim's 340B status, we believe that the Prescriber-Pharmacy Methodology for identifying 340B units is not in contradiction with policies set forth in Medicare Drug Price Negotiation Program guidance. CMS outlines in section 40.4.5 of the Medicare Drug Price Negotiation Program final guidance for initial price applicability year 2027 and for initial price applicability year 2028 that a "provider or prescriber ID alone generally will not constitute sufficient evidence that a claim was 340B-eligible,"[362, 363] meaning a manufacturer must be able to provide other evidence to conclude a claim was 340B-eligible to fulfill its statutory obligations under section 1193(d)(2) of the Act. CMS applies this same principle to the Prescriber-Pharmacy Methodology outlined in this final rule, which also does not use provider or prescriber ID alone and instead uses a robust data analysis where the prescriber NPI is representative of a select input in the ultimate identification and assessment related to the potential 340B eligibility of a Part D claim.

Comment: Many commenters stated that the proposed claims-based methodology relies on missing or incomplete information. A few commenters stated that missing information may lead manufacturers to be held responsible for inflation rebates on claims that were replenished at a 340B discount. A few commenters stated that the claims-based methodology does not actually identify whether the prescription was filled for a drug purchased at the 340B price and only informs if the claim may have been 340B -eligible. Another commenter stated the OPAIS registration of a contract pharmacy with a covered entity does not preclude that pharmacy from dispensing 340B and non-340B units.

Some commenters stated that the OPAIS database does not contain a complete accounting of the whole universe of registered covered entities, may not contain the requisite information (such as all covered entities' registered MPNs or NPIs) to match accurately using the proposed Prescriber-Pharmacy methodology, and that not all contract pharmacies are correctly identified in the 340B OPAIS database.

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[362] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, *https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

[363] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

Further, many commenters acknowledged that the 340B OPAIS database may not account for "in-house" pharmacies of covered entities and that these pharmacy types are often not listed as contract pharmacies of covered entities on the 340B OPAIS database and would not capture 340B -eligible claims from this pharmacy type. A few commenters reported that the sector of pharmacies occupied by covered entity owned or covered entity "in-house" pharmacies has experienced significant growth because of covered entities investing in this space, outpacing the growth of other types of pharmacies. A few commenters recommended that CMS consider matching addresses listed in the "Shipping Addresses" section of the 340B OPAIS database as additional locations that could be dispensing 340B-eligible claims on behalf of a covered entity in order to more accurately identify "in-house" pharmacies or pharmacies dispensing 340B-eligible drug on behalf of a covered entity but not registered as contract pharmacies in the 340B OPAIS database. A commenter noted that the Medicaid Exclusion File (MEF) on the 340B OPAIS database is not designed to represent a comprehensive inventory of all covered entities' billing information.

Response: We appreciate the commenters' feedback. We acknowledged in the CY 2026 PFS proposed rule that not all pharmacies that dispense 340B-eligible drugs are registered in the 340B OPAIS database, including covered entities with "in-house" pharmacies, and that units of 340B-eligible drugs dispensed from pharmacies not registered in the 340B OPAIS database would not be identified as 340B-eligible using the Prescriber-Pharmacy Methodology, and we solicited comment on ways to improve the methodology to enhance completeness and accuracy of the data sources used. To address this limitation, we are adopting the approach recommended by interested parties to use the "Shipping Addresses" listed for each covered entity in the OPAIS database as an additional location that may dispense 340B-eligible drugs on behalf of the covered entity. By incorporating this enhancement to the Prescriber-Pharmacy Methodology as suggested by commenters, based on preliminary analysis, CMS expects to identify additional "in-house" pharmacies and pharmacies that are not registered as contract pharmacies in the 340B OPAIS database, but that do dispense 340B drugs on behalf of a covered entity. We will use a similar matching methodology to the methodology described in the CY 2026 PFS proposed rule to match contract pharmacy locations to registered pharmacy locations in the NCPDP database using geocode matching, fuzzy string matching, a cartesian join, and manual review as needed to identify NPIs that are associated with the

"Shipping Address." With regards to the comment about the MEF, the MEF is used exclusively for purposes of the Medicaid program and is not used in the Prescriber-Pharmacy Methodology.

We believe adopting these additional measures and incorporating them into the already robust methodologic approach described addresses the concerns raised by commenters about using the 340B OPAIS database in CMS' methodology for calculating the number of 340B units to be removed from the Part D inflation rebate calculations. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based solely on Part D claims submitted to CMS by the covered entity. We believe that the Prescriber-Pharmacy Methodology as proposed in this final rule, which incorporates enhancements to address identified limitations such as "in-house" pharmacies, as recommended by commenters, represents an appropriate accounting of 340B units to remove in the calculation of a manufacturer's inflation rebate liability. We believe this approach is an additional measure to further address the limitations raised by commenters.

Comment: A commenter requested that CMS consider allowing manufacturers to report errors in the prescriber-pharmacy pairings to improve the accuracy of the Prescriber-Pharmacy Methodology. Further, a few commenters requested that CMS allow manufacturers to identify and submit data to correct perceived errors in the calculation of 340B units using the Prescriber-Pharmacy Methodology.

Response: We appreciate the comments requesting opportunities to identify errors in the Prescriber-Pharmacy Methodology through identification of errors in prescriber-pharmacy pairings or through reporting of errors in the calculated number of 340B units based on the Prescriber-Pharmacy Methodology. Section 1860D-14B(f) of the Act, codified at § 428.403(a)(1), precludes administrative or judicial review of the determination of units as set forth at § 428.203, the determination of whether a drug is a Part D rebatable drug as set forth at § 428.101, and the calculation of the rebate amount as set forth at § 428.201(a) inclusive of any reconciled rebate amount. As explained in the CY 2025 final rule (89 FR 98307), the Suggestion of Error process will be limited to mathematical steps involved in determining the rebate amount, and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process. Therefore, CMS decline the request to allow manufacturers to

report errors in the calculated number of 340B units from the Prescriber-Pharmacy Methodology through the Suggestion of Error process or a separate process.

As earlier stated, because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based solely on Part D claims submitted to CMS by the covered entity. Therefore, we believe that the Prescriber-Pharmacy Methodology as described in this final rule, which incorporates enhancements to address identified limitations such as "in-house" pharmacies, as recommended by commenters, represents an appropriate accounting of 340B units to remove in calculation of a manufacturer's inflation rebate liability. We anticipate that after adopting the measures described to reduce the risk of undercounting 340B units, its Prescriber-Pharmacy Methodology using the 340B OPAIS database provides a reasonably accurate identification of the total number of 340B units for the applicable period. Additionally, as earlier outlined in more detail, we understands that the determination of potential 340B-eligibility of a PDE record using the methodology described herein does not necessarily mean that the covered entity replenished (or can in the future replenish) the units at the 340B price, and we therefore believe it is more probable that the proposed claims-based methodology may overestimate the number of units that are units for which a manufacturer provided a discount under the 340B Program, than undercount 340B units.

Comment: Many commenters provided feedback that the proposed claims-based methodology would result in an overestimation of eligible Part D 340B claims to be removed in the calculation of a manufacturer's rebate liability. Some commenters noted that some prescribers may only "moonlight" at covered entities and that the proposed methodology would not consider that such providers have claims that are prescribed on behalf of the covered entity and some claims that are prescribed in association with a non-340B entity, resulting in the misclassification of claims as 340B-eligible. A commenter believed that the range of potentially eligible 340B claims reported in the estimation was substantially greater than prior estimates of the program's size but did not provide confirmatory evidence. Some commenters noted that because of restrictions put in place by drug manufacturers on which pharmacies can replenish 340B drugs, the identification of a claim as 340B-eligible did not mean that the pharmacy had access to replenish the drug at the 340B price and would result in an overstatement of the number of 340B units. A few

commenters raised other reasons as to why the proposed methodology would overestimate the number of 340B-eligible units including: (1) it would classify controlled substances as 340B-eligible when they are generally excluded from 340B eligibility due to the complexities related to procurement; (2) prescriptions may not qualify because they do not meet the patient definition; (3) contract pharmacies fill both 340B -eligible and non-340B -eligible claims; and (4) not all services within a covered entity are 340B -eligible. Some commenters expressed concern that the overestimation of 340B-eligible units may have negative consequences for 340Bcovered entities. A few commenters expressed concern that by overestimating the number of 340B -eligible claims, CMS would reduce the manufacturers' inflation rebate liability and hamper the program's intent, as they believed it, which is to control drug costs for Medicare beneficiaries. A few commenters also expressed concern that an overestimation of 340B-eligible claims would misrepresent the impact of the 340B Program and could result in further restrictions on access to 340B drugs for covered entities from manufacturers.

Response: We appreciate the feedback provided by these commenters. We acknowledged in the CY 2026 PFS proposed rule that the proposed Prescriber-Pharmacy Methodology is likely to overestimate the number of 340B -eligible claims. However, at this time there does not exist an available accounting that includes information on whether a claim for a Part D rebatable drug is 340B -eligible and uses a drug purchased at the 340B price to fill the claim or is associated with a corresponding 340B purchase. Because of the lack of a comprehensive source of information related to 340B claim eligibility and 340B discounted drug utilization, we intend to leverage the publicly available data and claims data available to the agency to determine the number of 340B units to remove from a manufacturer's rebate liability calculation. As described earlier, this methodology is grounded in previously published literature and uses publicly available information (for example, the OPAIS database) as well as claims-level data to determine the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program for the last 3 calendar quarters of the applicable period that begins on October 1, 2025 to implement section 1860D-14B(b)(1)(B) of the Act.

In response to the commenters who expressed concern that an overestimation of the 340B-eligible claims would misrepresent the 340B Program's impact and result in further restrictions on the 340B Program, we remind interested parties that we are adopting the Prescriber-Pharmacy Methodology for use in

the Part D Drug Inflation Rebate Program only. Nothing in this final rule modifies a manufacturer's statutory obligations under section 340B(a)(1) of the Public Health Service Act.

Comment: Many commenters provided feedback on actions that CMS may take to clarify or improve the accuracy of identifying 340B -eligible claims in the claims-based methodology. A few commenters requested that CMS clarify whether units dispensed to Medicare Advantage (MA) beneficiaries would be counted and that such units should be accounted for. Another commenter recommended that CMS establish a minimum "threshold" for determining an affiliation between a provider or patient and a covered entity (for example, minimum number of claims, share of services at a given MPN). A commenter suggested that CMS consider a "greater of" approach, which would compare multiple methodologies and select the one that produced the highest estimate. A commenter requested that CMS and HRSA require contract pharmacies, "in-house" pharmacies, and covered entity-owned pharmacies to report additional information, such as NPI and Drug Enforcement Administration (DEA) number, to more easily identify pharmacies that are dispensing 340B drugs on behalf of covered entities. A few commenters requested that CMS collaborate with HRSA to revise the 340B patient definition, establishing a more defined nexus between the patient and provider, and to align any such revisions with the Prescriber-Pharmacy Methodology. A commenter suggested that CMS expand the proposed methodology also to include 340B purchase data. A few commenters requested that CMS evaluate the impact of the proposed HRSA 340B Rebate Model Pilot on the proposed claims-based methodology.

Response: We appreciate the commenters' feedback. In response to commenters who requested clarification as to whether MA beneficiaries would be counted, claims for MA beneficiaries are included in the PDE data, and the Prescriber-Pharmacy Methodology will identify potential 340B Part D units for these beneficiaries. However, the methodology does not use MA encounter data to construct the HRSA covered entity MPN-NPI affiliations. The primary reason for this is because the MA encounter data does not have the MPN populated. Regarding the comments related to exploring the nexus of the 340B patient definition and the Prescriber-Pharmacy Methodology and the impact of the HRSA Rebate Model Pilot on the Prescriber-Pharmacy Methodology, these comments are out of scope for this final rule because they address another program and topics beyond the scope of the Medicare Part D Drug Inflation Rebate Program.

We do not intend to adopt the recommended modifications to the claims-based methodology provided by these commenters at this time. We believe that the Prescriber-Pharmacy Methodology we have proposed, including the modifications outlined in this final rule, sufficiently identifies Part D units as 340B-eligible unless and until a different method to remove 340B units is proposed and finalized. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based solely on Part D claims submitted to CMS by the covered entity, therefore, we believe that the Prescriber-Pharmacy Methodology as established in this final rule, which incorporates enhancements to address identified limitations such as "in-house" pharmacies and covered entities that do not have MPN's listed in the 340B OPAIS database, as recommended and supported by commenters, represents an appropriate accounting of 340B units to remove in calculation of a manufacturers inflation rebate liability.

Comment: A few commenters inquired whether CMS has tested the proposed Prescriber-Pharmacy Methodology and whether CMS would make the results of such testing available.

Response: As stated in the CY 2026 PFS proposed rule, based on preliminary analyses of this claims-based methodology, for most Part D rebatable drugs, we expect to remove about 10 percent to 35 percent of the total number of units determined at § 428.203(a) used to calculate the total rebate amount determined at § 428.201(a). We emphasize that this approximation is preliminary and may vary significantly across different Part D rebatable drugs. CMS declines to publish the results of its preliminary analysis and believes interested parties can replicate the analysis following the methodology provided.

Comment: Some commenters noted that the Prescriber-Pharmacy Methodology may underrepresent 340B claims from grantee sites, such as Ryan White (RW) clinics or ADAPs. A few commenters noted that ADAPs are unique among covered entities and that CMS should consider alternatives to identifying 340B-eligible claims from these sites, such as allowing ADAPs to report data directly to CMS, to increase the accuracy of any proposed estimates. A commenter noted that an ADAP client's provider may be associated with a 340B or a non-340B entity and that linking the NPI of the provider to the ADAP is a challenging proposition. Additionally, the commenter noted that not all pharmacies used by ADAPs are registered in the OPAIS database as contract pharmacies. A commenter

recommended that CMS convene a technical advisory group better to inform the ADAP 340B claims identification process.

Response: We appreciate the feedback that commenters have identified regarding the uniqueness of RW clinics and ADAPs, as well as their intersections with the 340B Program and the proposed Prescriber-Pharmacy Methodology. We are not adopting the specific recommendations related to the reconciliation of 340B claims from ADAPs that were submitted by commenters, but CMS is making other modifications to the Prescriber-Pharmacy Methodology that we believe will improve our ability to identify 340B claims associated with RW clinics. Specifically, we are adopting the methodology to use data sources such as the CMS Integrated Data Repository to map 340B OPAIS database provided organizational NPIs to corresponding individual NPIs and MPNs to establish a supplemental list of prescriber NPIs that are associated with covered entities. Early analysis of this supplemental NPI approach to the Prescriber-Pharmacy Methodology revealed that the supplemental NPI approach was able to associate a higher proportion of additional providers associated with 340B grantee programs, such as RW clinics, than with other covered entity types, including disproportionate share hospitals and critical access hospitals than the Prescriber-Pharmacy Methodology alone. This greater provider association for covered entity grantees leads to a higher number of Part D claims being determined as potentially 340B-eligible from these covered entity types. Although we acknowledge the concerns that commenters raised regarding identification of 340B-eligible claims from ADAPs, our preliminary analyses mitigate the impact of such concerns, as the percentage of 340B units identified for drugs commonly covered by ADAPs, such as antiretrovirals, is reasonably close to the average percentage of 340B units identified overall. We may consider methodological refinements in the future to further address commenters' feedback on ADAPs.

After consideration of public comments, we are adopting our proposal to implement the requirement in section 1860D-14B(b)(1)(B) of the Act and described in § 428.203(b)(2) to remove 340B units through the Prescriber-Pharmacy Methodology, with modification to incorporate certain commenters' recommendations to reduce the risk of undercounting of the 340B units to be removed from the calculation of rebatable units. Specifically, as adopted, the agency intends to incorporate recommendations to utilize the supplemental NPI approach using data sources such as the CMS Integrated Data Repository to map 340B OPAIS database provided organizational NPIs to corresponding individual NPIs and MPNs, as well as the

approach raised by certain commenters, as discussed earlier in this section, identifying additional pharmacies registered as "Shipping Addresses" of covered entities within the OPAIS data as part of the Prescriber-Pharmacy Methodology to determine the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program for the last three calendar quarter of the applicable period that begins on October 1, 2025 that is, January 1, 2026 through September 30, 2026, in order to implement section 1860D-14B(b)(1)(B) of the Act.

CMS considered an alternative methodology to the Prescriber-Pharmacy Methodology (hereinafter, "the Beneficiary-Pharmacy Methodology") in the CY 2026 PFS proposed rule (90 FR 32641). In contrast to the Prescriber-Pharmacy Methodology, the Beneficiary-Pharmacy Methodology would identify potentially 340B-eligible units (that would be treated as 340B units for purposes of effectuating the exclusion at § 428.203(b)(2)) as units associated with PDE records that are: (1) dispensed by a pharmacy currently under contract with a covered entity, and (2) for beneficiaries who receive care from a covered entity affiliated with that pharmacy. To implement this methodology, CMS would create beneficiary-pharmacy pairs that meet the defined criteria by combining two files: (1) the same monthly file used in the Prescriber-Pharmacy Methodology that links covered entities (identified by MPN or NPI) with pharmacy NPIs for those covered entities, and (2) a monthly file containing beneficiaries associated with PDE records from the applicable year and the MPNs of providers from which those beneficiaries received care. CMS would generate this latter file by identifying beneficiary-month combinations based on the date of dispense on the PDE record, then determining the MPNs (or NPIs) where those beneficiaries received services during those months. The identification of MPNs (or NPIs) where beneficiaries receive care would rely on inpatient, outpatient, and professional claims within both Medicare FFS and Medicare Advantage claims data.

To establish beneficiary-pharmacy pairs, CMS would merge the two files described previously in this final rule by MPN and month, producing month-level combinations that link beneficiaries to contract pharmacies. These combinations would reflect the universe of beneficiaries who receive services at a covered entity and the associated contract pharmacies for those covered entities. To identify associated PDE records, CMS would filter for records with beneficiary ID, service provider ID, and claim date combinations

that align with one of the beneficiary-pharmacy-month combinations. For any PDE record that matches these pairings, the units associated with the record would be considered 340B units.

While CMS noted its anticipation that the degree of overlap between the Prescriber-Pharmacy Methodology and the Beneficiary-Pharmacy Methodology would be high, CMS stated that it may consider revisions to the Prescriber-Pharmacy Methodology based on further analyses of the Beneficiary-Pharmacy Methodology—such as defining 340B units using the union of units identified by both methodologies or refining the Prescriber-Pharmacy Methodology. We solicited comments on the potential benefits and drawbacks of using a Beneficiary-Pharmacy Methodology and on whether a Beneficiary-Pharmacy Methodology could be combined with the Prescriber-Pharmacy Methodology to validate 340B units identified, such as via a union of the two methodologies.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters provided suggestions to CMS regarding the differences and benefits of the Prescriber-Pharmacy Methodology compared to the Beneficiary-Pharmacy methodology. These commenters believe that the Prescriber-Pharmacy Methodology would provide a more accurate representation of potentially 340B -eligible claims than the Beneficiary-Pharmacy approach. A few commenters noted that they thought the Beneficiary-Pharmacy Methodology would lead to an underrepresentation of 340B units, citing, for example, the additional complexity involved in beneficiary matching and the underrepresentation of medications taken on a recurring basis. A commenter recommended using both of the proposed methodologies to maximize 340B claim identification.

Response: We appreciate commenters' feedback on this alternative methodology. As previously outlined, we intend to move forward with the proposed Prescriber-Pharmacy Methodology to determine the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program for the last 3 calendar quarters of the applicable period that begins on October 1, 2025, to implement section 1860D-14B(b)(1)(B) of the Act. Based on CMS' analysis and feedback provided by commenters, we believe that the Beneficiary-Pharmacy Methodology is likely more operationally complex, less accurate, and does not offer a significant improvement as a replacement for or use in conjunction with the Pharmacy-Prescriber Methodology.

After further consideration and taking into account the comments received from commenters on the proposed Beneficiary-Pharmacy Methodology, we are not adopting the proposed Beneficiary-Pharmacy Methodology for the applicable period that begins on October 1, 2025.

Comment: A commenter encouraged CMS to develop a 340B units identification methodology to incorporate purchase data to match covered entity acquisitions with Part D claims. Such data includes wholesaler name, wholesaler account number, NDC-11, invoice date, quantity, invoice number, ship-to-pharmacy NPI, and 340B ID.

Response: We appreciate the commenter for sharing their ideas. We do not have access to 340B acquisition data that is specific for 340B purchases associated with Medicare Part D claims. Based on our consideration of comments received, we are adopting our claims-based methodology as proposed to implement the exclusion required by section 1860D-14B(b)(1)(B) of the Act. We will also assess submissions made to the 340B repository to evaluate the feasibility and desirability of future rulemaking to provide for use of such a repository to identify 340B units for the exclusion required by section 1860D-14B(b)(1)(B) of the Act.

iii. Alternative Policy Considered: Estimation Percentage Using PVP and AMP Data

As described in section III.E.3.c.i of this final rule, CMS considered an alternative estimation methodology to remove units from the total number of units dispensed of a Part D rebatable drug for each applicable period that would be based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. This alternative estimation methodology was proposed in the CY 2025 PFS proposed rule (89 FR 61969), in which we proposed to use an estimation percentage that would equal the total number of units purchased by covered entities under the 340B Program for an NDC-9, divided by the total units sold of that NDC-9. We include more detail in section III.E.3.c.i of this final rule regarding the estimation percentage methodology originally discussed in the CY 2025 PFS proposed rule.

We acknowledged some limitations of this methodology in the CY 2025 PFS proposed and final rules, as noted in section III.E.3.c.i of this final rule. After further consideration of comments received in response to the CY 2025 PFS proposed rule, we are no longer pursuing this policy at this time but may consider it in future rulemaking. We did not solicit comment on this approach. However, where commenters

provided comparison or analysis of this approach as it relates to the proposed Prescriber-Pharmacy Methodology, we have summarized those comments and responded accordingly earlier in this final rule.

iv. Establishing a Medicare Part D Claims Data 340B Repository

In the initial Medicare Part D Drug Inflation Rebate Guidance, we solicited comments on the best mechanism to identify 340B units dispensed under Part D.[364] CMS discussed requiring the dispensing entity to include a 340B claims indicator on the Part D drug claim to be included in PDE records.[365] Many commenters disagreed that requiring the dispensing entity to include a 340B claims indicator on the Part D drug claim to be included on the PDE record was the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with both point-of-sale claims indicators and retrospective 340B identifiers. In addition, a wide array of interested parties recommended that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B claims dispensed under Part D. Interested parties suggested that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors.

In response to this feedback from interested parties, in the CY 2025 PFS proposed rule (89 FR 61971 through 61972) we solicited comments on establishing a repository in a future year of the Medicare Part D Drug Inflation Rebate Program to comply with the requirement under section 1860D-14B(b)(1)(B) of the Act that CMS shall exclude from the total number of units for a Part D rebatable drug those units for which a manufacturer provided a discount under the 340B Program. In the CY 2025 PFS proposed rule (89 FR 61971), we stated that this approach would require that covered entities submit certain data elements from Part D 340B claims to the repository, and we solicited comments on such a requirement. In the CY 2025 PFS final rule (89 FR 98293), we stated that we would explore avenues to implement section 1860D-14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provided a discount under the 340B

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[364] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

[365] Currently, a pharmacy may voluntarily use the value of "AA" in the Submission Type Code (D17-K8) field to indicate use of a 340B drug at the time of the adjudication or dispensing of the claim. See: National Council on Prescription Drug Program (NCPDP) 340B Information Exchange Reference Guide Version 2.0, June 2019, *https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.*

Program starting January 1, 2026, through the establishment of a repository. To inform policy development for this rulemaking, we reviewed and considered the comments received on the CY 2025 PFS proposed rule.

In the CY 2026 PFS proposed rule (90 FR 32641 through 32644), we proposed to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. We proposed to allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository.

We proposed that the 340B repository would receive, via submission by each covered entity that chooses to submit data to the repository, data elements (as described in the next section) from all of that covered entity's Part D 340B claims with dates of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provided a discount under the 340B Program ("Part D 340B claims") for all covered Part D drugs billed to Medicare Part D. As requested by interested parties in comments on the initial Medicare Part D Drug Inflation Rebate Guidance and the CY 2025 PFS proposed rule, the 340B repository would allow covered entities to submit these data directly to CMS (or a contractor), rather than through claims that dispensers submit to Part D plan sponsors. We proposed that CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims; that is, the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data.

Under this process, we proposed that CMS would require a certification from covered entities that the covered entity had submitted all Part D 340B claims with dates of service during the relevant time period and that the data elements from all claims submitted to the 340B repository were from verified 340B claims and, to the best of the covered entity's knowledge, their submission included all Part D 340B claims for the covered entity at the time of submission for the applicable period. We proposed that CMS would require covered entities to certify the completeness and accuracy of the data submitted, and require that the submitter is authorized to submit on behalf of the entity. We stated in the proposed rule that we

are exploring approaches to confirming completeness and accuracy of data submissions to the 340B repository. We proposed that CMS would match the stored data elements in the 340B repository to PDE transactions for each Part D rebatable drug dispensed during the applicable period. We proposed that if we determine that the data reported to the repository is usable and reliable and, in the future, propose and finalize a policy to use such data to exclude 340B units from rebate calculations, then units associated with PDE transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provided a discount under the 340B Program and therefore would be removed from the total number of units used to calculate the total rebate amount. We stated in the proposed rule that we understand the importance of maintaining the confidentiality of data submitted to the 340B repository. We also stated that we do not expect concerns about the privacy of data submitted to the 340B repository, as this data would not be made available to external parties, including manufacturers and Part D plan sponsors.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to establish a 340B repository. A few commenters stated that the repository is a positive step because it would allow CMS to more accurately identify 340B-eligible units than other policies CMS has proposed for this purpose. A few commenters recommended that CMS ensure the repository is a neutral clearinghouse and, if CMS engages with a third-party to operate the repository, that the party is free of conflicts of interest. A few commenters stated that the repository should leverage existing systems where possible, including solutions that are already functional and integrated with manufacturers, covered entities, and pharmacies.

A few commenters stated that they support the repository in conjunction with the use of 340B and non-340B claims indicators. A commenter recommended CMS use existing claims indicators rather than the repository, stating that this would maintain transparency and oversight without creating new burden. A commenter advised CMS to create a timeline for moving from the claims-based methodology to the use of 340B identified claims as soon as possible. A commenter requested that CMS to expedite testing of the repository. A commenter suggested that CMS use data reported to the repository to reconcile rebate amounts for applicable periods beginning in 2025 and 2026.

Response: We appreciate the commenters' suggestion and support of the proposal to establish a repository. We are adopting the proposal to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. We will allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository. CMS intends to leverage existing processes and systems whenever possible. If CMS engages with a third-party to support the repository, protocols to address conflicts of interest will be followed. For example, CMS will implement safeguards such as firewalls or contractual limitations on usage of information to ensure that any third-party supporting the repository does not misuse information to which it obtains access in its role supporting the repository.

In response to the recommendations for the use of a Part D claims indicator for 340B claims and non-340B claims, we note that such a claims indicator is not currently required and acknowledge feedback received on the CY 2025 PFS final rule that requiring such a claims indicator has the potential to pose operational challenges, increase administrative burden, and may not always be accurate. In this final rule, we maintain that we are not pursuing a 340B claims indicator policy at this time.

Comment: Many commenters supported strict privacy and data security protections for data submitted to the repository. Some commenters stated that data security standards should be clearly set forth in user agreements. Many commenters stated that CMS should ensure data submitted to any Medicare Part D claims data repository is protected from other parties, including manufacturers. A commenter stated that if any claims-specific data is provided to manufacturers as part of the Medicare Prescription Drug Inflation Rebate Program, this could shift the cost of the 340B Program from manufacturers to beneficiaries and taxpayers because manufacturers could withhold formulary placement rebates. By contrast, many commenters stated that CMS should provide manufacturers with access to data submitted to the repository to verify rebate calculations, with a few commenters stating that sharing data with manufacturers would align with the Trump Administration's transparency goals. A commenter requested more information about a dispute resolution process if inaccurate data is found in the repository that leads to a manufacturer paying an inappropriate rebate.

Response: We appreciate the commenters' feedback. As we stated in the CY 2026 PFS proposed rule (90 FR 32642), we understand the importance of maintaining the confidentiality of data submitted to the 340B repository. Therefore, this data will be for official use only and shall not be disseminated, distributed, or copied to persons not authorized to receive the information, including manufacturers and Part D plan sponsors. We affirm our commitment to protect sensitive and confidential data submitted by covered entities and continue to acknowledge the importance of data security. The repository will be designed to comply with all applicable Federal security laws, regulations, and Department of Health and Human Services (HHS) policies, including but not limited to those related to data protection and information security.

We decline to provide claim-level data to manufacturers regarding the 340B Program or other statutory exclusions of units from inflation rebate calculations as we do not believe this is necessary to operate the program at this time. The data submitted to the 340B repository will not be used to calculate inflation rebates unless and until we propose and finalize a policy to use such data to exclude 340B units from rebate calculations. Therefore, provision of data from the repository to manufacturers would not be useful for the purposes of assessing their rebate reports. In addition, section 1860D-14B(f) of the Act, codified at § 428.403(a)(1), precludes administrative or judicial review of the determination of units as set forth at § 428.203, the determination of whether a drug is a Part D rebatable drug as set forth at § 428.101, and the calculation of the rebate amount as set forth at § 428.201(a) inclusive of any reconciled rebate amount. As explained in the CY 2025 final rule (FR 98307), the Suggestion of Error process is limited to mathematical steps involved in determining the rebate amount and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process.

After consideration of public comments, we are adopting the policies as proposed.

v. Covered Entities to Submit 340B Claims Data to the 340B Repository

In the CY 2026 PFS Proposed Rule (90 FR 32642), we proposed that covered entities would optionally begin submitting the fields specified by CMS (as described further later in this section) to the 340B repository beginning in 2026 for Part D 340B claims with dates of service on or after January 1, 2026 to allow for CMS to begin usability testing for the 340B repository. CMS would not use the data submitted during the testing period to remove units from Part D inflation rebates unless and until a policy

to do so was proposed and finalized. We proposed that we expected that hospitals receiving Medicare Disproportionate Share Hospital (DSH) payments, Federally Qualified Health Centers (FQHCs), and Critical Access Hospitals (CAHs) would begin to submit data elements to the 340B repository during the testing period. CMS strongly encouraged all covered entities to submit data elements to the 340B repository during the testing period beginning in 2026, as this participation would allow for robust testing of data quality and completeness. It would also provide an opportunity for covered entities to develop and test their data submission processes. CMS proposed that it would address the possibility of mandatory reporting of data elements to the 340B repository by covered entities in future years in future rulemaking. CMS noted that many covered entities are providers and suppliers regulated by CMS under Title XVIII of the Act, including hospitals receiving DSH payments, CAHs and FQHCs. CMS noted that it was actively considering options for mandatory reporting to the 340B repository in the near future and recommended that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting.

We noted that we understand covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B-eligibility of claims using data submitted by covered entities and their contractors. We proposed to allow covered entities that choose to submit data to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. We proposed that covered entities would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf.

We proposed to require entities (whether a covered entity, or a vendor on their behalf) that choose to submit data to the 340B repository during the testing period beginning in 2026 to provide information identifying the covered entity, which could include information such as the covered entity's 340B ID and name as designated in the 340B OPAIS database, when submitting claim information to the 340B repository. We proposed to use the collected identifying information to: (1) perform analyses to assess suitability of the data for future use in removing 340B units; and (2) provide a means to follow up with the covered entity on questions related to claims data submission. In addition to this identifying information, we proposed to require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the following data elements from Part D claims for

covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy NPI; and (5) NDC-11. We proposed to use these data elements to match claims to PDE transactions and perform further analyses to assess suitability of the data for future use in removing 340B units from Part D inflation rebate calculations.

In the CY 2025 PFS proposed rule (89 FR 61971), we solicited comments from interested parties on the first four data elements in the list referenced in the previous paragraph ((1) Date of Service; (2) Prescription or Service Reference Number; (3) Fill Number; and (4) Dispensing Pharmacy NPI) and whether these data elements would be accessible to covered entities to submit to CMS. In comments on the CY 2025 PFS proposed rule and summarized in the CY 2025 PFS final rule (89 FR 98293), many interested parties recommended that CMS collect additional data elements, such as the NDC, stating that the NDC would help CMS better match the data submitted by the covered entity to the PDE data for Part D rebatable drugs dispensed during an applicable period. We believe that collecting the NDC would provide useful information for analysis of the data submitted, in addition to the four data elements on which we solicited comment in the CY 2025 PFS proposed rule, and which are the minimum elements that would be necessary to match a submission to a PDE transaction to exclude units from inflation rebate calculations, were the repository to be used for such purpose in the future. The NDC is also a required data element collected under an existing State-based program that operates to match and identify 340B units, similar to the 340B repository that we proposed to establish.[366] Therefore, we believe that requiring covered entities participating in the 340B repository during the testing period beginning in 2026 to submit the NDC in addition to the four data elements listed previously ((1) Date of Service, (2) Prescription or Service Reference Number; (3) Fill Number; and (4) Dispensing Pharmacy NPI) is reasonable and would not create substantial additional burden.

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[366] The State of Oregon allows 340B covered entities to avoid duplicate 340B discounts and Medicaid rebates when contracting with one or more retail pharmacies to dispense drugs purchased at the 340B price by using a retroactive 340B claims submission process. The NDC-11 is one required data element in Oregon's retroactive 340B claims submission process. See: *https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx*.

We are issuing an Information Collection Request alongside this final rule entitled "Information Collection Request (ICR) for the Medicare Prescription Drug Inflation Rebate Program under Section 11101 and 11102 of the Inflation Reduction Act (IRA)" (CMS-10930, OMB 0938-1485) for submission to the 340B repository (by covered entities that choose to submit) of certain data elements from all Part D 340B claims for all covered Part D drugs billed to Medicare Part D with dates of service during the relevant period. Section VI: The Collection of Information Requirements section of this final rule addresses the burden associated with the collection of data for the 340B repository. The ICR includes more details regarding how covered entities can submit data to the 340B repository, including the format for data submission.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported CMS establishing the proposed voluntary 340B repository in calendar year 2026. A commenter emphasized that covered entities are facing new requirements and challenges and stated that the proposed testing period is critical to assess CMS' and providers' investment of time and resources into reporting to the repository.

By contrast, many other commenters requested that CMS make reporting to the repository mandatory for covered entities and their contractors. A few of these commenters stated that without a mandatory requirement for submission to a repository, the repository will not be able to be used to fulfill the legal requirement to remove 340B units. Some commenters stated that a mandatory repository would provide a more comprehensive and accurate method for identifying and excluding 340B units than a voluntary repository. A commenter recommended that if CMS does not implement a requirement to submit to the repository initially, it should make submission mandatory for key types of large hospitals such as DSH and Rural Referral Centers (RRCs), stating that these hospitals have sophisticated software to manage their 340B programs which could streamline submission to the repository. A few commenters requested that CMS clarify that the repository will be mandatory in 2027, which they state could encourage covered entities to use the repository when it is voluntary in 2026. A few commenters stated that under the inflation rebate invoicing timeline, CMS could establish and test a repository and require covered entities to retrospectively report 340B claim data for 2026 to the repository once it is operational.

Some commenters expressed concern that with voluntary reporting, the repository is unlikely to receive submissions from a significant number of covered entities. A commenter stated that time, system set up, and an attestation requirement reduce incentives for covered entities to submit data to a voluntary repository. Another commenter stated that covered entities have consistently opposed efforts to increase transparency in the 340B Program through broader access to claims data. A few commenters stated that low submission rates could impede CMS' ability to acquire the necessary data to test the repository. Another commenter stated that hospitals have had poor compliance rates with CMS-mandated price transparency reporting and, therefore, the commenter has little confidence that voluntary reporting to the repository would meet the statutory requirement to exclude 340B units. A few commenters recommended that CMS engage with interested parties and provide data protections before moving to a mandatory repository. A few commenters stated that CMS should provide a timeline by which the 340B data collection will transition from voluntary to a mandatory requirement.

A few commenters requested CMS work with HRSA to establish an enforcement mechanism tied to mandatory compliance with the repository. A few commenters recommended that CMS consider making data submission to the repository mandatory by relying on its authority at section 1121 of the Act to establish "a uniform system for the reporting," of "discharge and bill data" by facilities and organizations, in addition to general CMS authorities related to organizations enrolled in Medicare. A few commenters recommended CMS make data submission to the repository mandatory by relying on IRA rulemaking authority and general rulemaking authority under sections 1102(a) and 1871(a)(1) of the Act to establish requirements for Medicare providers through Conditions of Participation. These commenters emphasized that covered entities that do not submit data to the repository could be considered to be in violation of the Conditions of Participation and could be subject to a range of actions up to and including termination of their provider agreements.

Response: We appreciate the commenters for their input and recommendations. We are adopting the proposal to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. We decline to provide a timeline under which we would move to a mandatory

repository, but as we stated in the proposed rule, we are actively considering options for mandatory reporting to the 340B repository in the near future and we recommend that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting. We expect that hospitals receiving Medicare DSH payments, FQHCs, and CAHs will begin to submit data elements to the 340B repository during the testing period. We encourage all covered entities to submit data elements to the 340B repository during the testing period beginning in 2026, as this participation would allow for robust testing of data quality and completeness.

To the commenters that stated that without a mandatory requirement, the repository will not be able to fulfill the legal requirement to remove 340B units from inflation rebate calculations, we note that the repository will not be used at this time to fulfill the legal requirement to remove 340B units, but rather to allow for robust testing of data quality and completeness to allow CMS to assess whether such data could be used to identify and remove 340B units for purposes of calculating Part D inflation rebates in a future applicable period following proposal and finalization of a policy to do so. It will also provide an opportunity for covered entities to develop and test their data submission processes. We appreciate the recommendation to engage with interested parties and provide data protections before moving to a mandatory repository, and we plan to continue to engage with interested parties and ensure that data is protected as we consider options for mandatory reporting to the 340B repository.

Finally, we also appreciate the comments and input related to authorities that the agency may rely on to implement a mandatory reporting requirement to the repository and conduct enforcement related to reporting to the repository. We will consider them in connection with any future rulemaking we may undertake for adoption of a mandatory reporting requirement.

Comment: Many commenters stated that data collected in the repository should be used only for inflation rebate purposes. A few commenters stated that if CMS were to decide to use data submitted to the repository for other programs outside the Medicare Part D Drug Inflation Rebate Program, CMS should provide ample notice, justification, and an opportunity for interested parties to provide feedback. A commenter requested that CMS clarify if the repository will be integrated with the Medicare Transaction Facilitator Data Module under the Medicare Drug Price Negotiation Program. Another commenter stated that HHS should not impose two separate and overlapping data submission

requirements on covered entities under the 340B repository and HRSA's 340B Rebate Model Pilot Program.

By contrast, some commenters stated that the repository should serve as more than just a resource for the Medicare Part D Drug Inflation Rebate Program and could be a centralized source to identify 340B-eligible claims across HHS programs. A few of these commenters stated that CMS should work with HRSA to establish a repository with expanded scope that would support transparency across the 340B Program. A few commenters recommended the repository be populated with claim-level data from the HRSA 340B Rebate Model Pilot Program for participating drugs. A commenter stated that data submitted to the repository should be used to monitor misuse of the 340B Program by comparing data submitted to the 340B repository to data submitted under HRSA's 340B Rebate Model Pilot Program. Some commenters stated that the information submitted to the repository could be used in the administration of other programs, such as the Medicare Drug Price Negotiation Program.

A commenter expressed interest in how the data submitted to the repository may be used, suggesting that the data the repository would collect could offer significant value if used for public health trends and drug price modeling. This commenter stated they would be supportive of the repository if the goal of the repository was to better track revenue and provide more transparency and accountability to resolve disputes in addition to validating 340B product data.

Response: We appreciate the commenters for their input and recommendations. At this time, any data submitted to the repository will only be used to begin usability testing to assess usability for the purpose of removing 340B units under the Medicare Part D Drug Inflation Rebate Program. If we were to decide to use data submitted to the repository for other programs outside the Medicare Part D Drug Inflation Rebate Program, we would provide notice, justification, and an opportunity for interested parties to provide suggestions on the proposal.

Comment: Many commenters supported the claims data elements that CMS proposed for submission to the 340B repository. Many commenters stated that the five data elements that CMS proposed are appropriate for submission to the repository and do not present overly burdensome requirements or put protected health information at risk. A few commenters stated that the proposed data elements represent the necessary information to accurately match to PDE records and that the proposed

elements could be easily matched to data from Medicare Part D data to identify 340B units to remove. A few commenters recommended CMS minimize the number of data elements for covered entities to submit to the repository. A commenter recommended CMS define data elements and submission timelines for submission to the repository.

Some commenters recommended CMS align the data elements to submit to the repository with the data elements from HRSA's 340B Rebate Model Pilot Program to increase efficiency. A commenter stated that CMS should collect 340B data for all segments of the market rather than only Part D claims, stating that these changes would streamline the submission process for covered entities.

A commenter recommended that CMS collect several additional data fields, such as the Date Prescribed, RX Number, Prescriber ID, Service Provider ID, and BIN/PCN. A commenter recommended CMS finalize the data elements proposed with the addition of the "Quantity Dispensed" element. This commenter stated that covered entities tend to submit inaccurate, incomplete, or variable data in the Quantity Dispensed field. A commenter stated that the proposed "Fill Number" data element is not an element routinely collected or used by ADAPs and should not be a required field for submission to the repository by ADAPs. A commenter recommended CMS add the original purchase date of the units dispensed as an additional data element. A commenter, in apparent conflation of the Prescriber-Pharmacy Methodology and the repository, stated that CMS should avoid relying on NPI for prescribers or contract pharmacy identifiers to identify 340B claims, stating that this would likely cause confusion and misidentification. A commenter recommended CMS include prescriber identification as a required data element for submissions to the repository. A few commenters recommended that CMS work with interested parties to identify data elements that minimize burden on ADAPs as much as possible.

Response: We appreciate the commenters' feedback and recommendations related to the data elements proposed for submission to the repository. We intend to minimize burden on covered entities while collecting the minimum elements that would be necessary to match a submission to a PDE transaction to exclude 340B units from inflation rebate calculations, were the repository to be used for such purpose in the future. We appreciate the commenters who submitted recommended additional data elements to collect and the commenters who supported the proposed data elements.

In the interest of minimizing burden on covered entities while collecting sufficient information to match a submission to a PDE transaction to exclude units from inflation rebate calculations, we are adopting the requirement that entities (whether a covered entity, or a vendor on their behalf) that choose to submit data to the 340B repository during the testing period provide information identifying the covered entity, which could include information such as the covered entity's 340B ID and name as designated in the 340B OPAIS database, when submitting claim information to the 340B repository. In addition to this identifying information, we are adopting the requirement that covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 must submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service; (2) Prescription or Service Reference Number; (3) Fill Number; (4) Dispensing Pharmacy NPI; and (5) NDC-11. We will use these data elements to match claims to PDE transactions and perform further analyses to assess suitability of the data for future use in removing 340B units from Part D inflation rebate calculations. In response to the comments regarding ADAP programs and the Fill Number data element, we believe the data elements we are adopting to collect in the 340B repository minimize burden on covered entities while providing the information needed to match submitted data elements to PDE transactions. For Part D claims, the Fill Number data element is required information to accurately associate the submitted data elements to the correct corresponding PDE record.

Comment: A few commenters stated that submitting data to the repository would not be overly burdensome since entities are already developing infrastructure and operational workflows needed to prepare to submit similar data for a set of drugs that will be included in the HRSA 340B Rebate Model Pilot Program. A commenter supported the proposal to allow third party administrators to transmit that data to the repository on behalf of covered entities.

Some commenters advised CMS to minimize burden on covered entities reporting to the repository. A few commenters stated that the process of identifying claims should not shift costs or burden onto pharmacies or prescribers. A commenter requested CMS finalize the proposal to receive data directly from the covered entity, and not through any payer or manufacturer. A commenter requested that

CMS clarify that pharmacies are not required to provide information to the repository, and that only covered entities are voluntarily providing this information.

A commenter interpreted CMS' proposal as requiring covered entities to begin submitting data fields to the 340B repository in 2026 and stated that this requirement would have significant implications for the Indian Health Service (IHS) as IHS facilities operate with limited staff and resources, and the commenter stated that this data collection could be used to restrict 340B savings. A commenter raised concerns regarding administrative costs and cash-flow volatility for small participants if there are new rebate obligations. A commenter recommended that CMS withdraw the requirement to submit to the repository as it would create an overwhelming administrative burden for rural facilities and stated that CMS should work with payers and pharmacies that already have this data. A commenter raised concern about burden for hospital neurology departments and outpatient practices, stating that the availability of the data elements is variable. This commenter recommended that CMS track additional administrative burden associated with submitting data to the repository and devise a strategy to minimize burden without reducing the value of the repository.

A few commenters recommended that, to reduce burden on covered entities, CMS remove the proposed requirement that covered entities certify that the data elements submitted to the 340B repository are from verified Part D 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for the applicable period. By contrast, a commenter recommended CMS finalize the proposed provision to require covered entities to complete this certification.

A commenter stated that they do not support the repository because imposing duplicative submission requirements puts the stability of the 340B Program at risk. A few commenters stated that submitting data to the repository will substantially increase burden on providers and that providers would need to devote significant resources to ensure compliance, which could divert resources from direct patient care. For these reasons, a commenter suggested CMS use the claims-based methodology to identify Part D 340B claims and abandon the repository approach, including any future mandatory data repository. A commenter recommended that CMS allow State ADAP programs to submit direct purchase and rebate data to the repository.

Response: We appreciate the commenters' feedback and recommendations. We are adopting the proposal that the 340B repository will be established and will begin accepting voluntary submissions from covered entities of the fields specified by CMS beginning in 2026 for Part D 340B claims with dates of service on or after January 1, 2026 to allow for CMS to begin usability testing for the 340B repository. We will not use the data submitted during the testing period to remove units from Part D inflation rebates unless and until a policy to do so is proposed and finalized.

In developing the data elements for submission and process for voluntary submission to the repository, we considered how to minimize burden on covered entities. We do not intend to receive data from pharmacies, manufacturers, or plans on the covered entity's behalf. As we stated in the proposed rule, we understand covered entities typically contract with vendors, such as 340B third-party administrators, to determine 340B-eligibility of claims using data submitted by covered entities and their contractors. We will allow covered entities that choose to submit data to the repository to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf if they would like to do so. At this time, we are not collecting direct purchase or rebate data in the 340B repository but we note that if ADAPs are covered entities and provide coverage for a Part D 340B claim, they can submit the data elements from that claim to the 340B repository.

We appreciate the commenters who submitted comments on the proposed requirement that covered entities certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for the applicable period. We do not have access to data to validate and ensure accuracy of submitted data, therefore we find this certification necessary to ensure completeness and accuracy of data submissions to the 340B repository. We are adopting the requirement that covered entities must certify the completeness and accuracy of the data submitted.

We disagree that the 340B repository puts the stability of the 340B Program at risk. A wide array of interested parties commented on the CY 2025 PFS proposed rule and previous CMS policymaking documents recommending that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B claims dispensed under Part D. Interested parties

advised that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors, and we believe this structure will not create risk for the 340B Program.

Comment: A few commenters advised CMS to engage with interested parties related to establishing the repository. A commenter encouraged CMS to collaborate with interested parties to ensure that the repository is established effectively and securely so that covered entities can meaningfully participate. A commenter recommended CMS provide a deadline of when the repository will be live and report on its testing of the repository's data matching regularly. A commenter stated that, if voluntary reporting to the repository is lower than CMS expected, CMS should engage with interested parties to understand why and improve voluntary participation.

A commenter requested that CMS consult with HRSA and provide educational resources and training related to submitting data to the repository that would lower administrative burdens on pharmacists. A commenter requested that CMS convene an advisory group to assist in finalizing and implementing policy related to ADAPs submitting data to the repository and suggested interested parties to serve as representatives for the group.

Response: We appreciate the commenters' feedback and recommendations. We welcome engagement with interested parties, including on topics such as data submission requirements and timing, as we work to operationalize the repository. We will share more information about the repository operationalization as soon as possible and will work to engage with interested parties, including those representing ADAPs, to understand any barriers to participation. We will also consider how to provide useful training and resources related to submitting data to the repository that would lower the administrative burdens.

After consideration of public comments, we are adopting the policies as proposed for covered entities to submit Part D 340B claims data to a 340B repository.

vi. Timing Requirements for Covered Entity Submissions to a Medicare Part D Claims Data 340B Repository

In the CY 2026 PFS Proposed Rule (90 FR 32643), CMS noted that it expected the Medicare Part D claims data 340B repository to launch in Fall 2026, meaning it would be available to collect 340B data

from covered entities for claims with dates of service on or after January 1, 2026. This remains CMS's expectation. To foster robust data reporting by covered entities, CMS understands that covered entities will need time to develop a process for collecting the 340B data elements described previously in this final rule and preparing the data in the form and manner prescribed by CMS. Additionally, given the variety in the scope of provider types and organizations that participate in the 340B Program, CMS recognizes the amount of preparation time varies. In consideration of these factors and the anticipated launch date for the 340B repository in Fall 2026, we proposed to require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the fields specified by CMS to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. Covered entities that choose to submit data should submit data elements related to Part D 340B claims with dates of service on or after January 1, 2026. At a point in the future, CMS will provide a deadline that CMS believes will allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. CMS will provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate ICR is finalized. During the rest of the testing period, CMS anticipates that covered entities will be expected to report data on a quarterly basis within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2026, through December 31, 2026, covered entities that choose to submit data elements from Part D 340B claims would submit the data to the 340B repository no later than March 31, 2027. We proposed that the data from these submissions would be used to assess the usability of such data to implement section 1860D-14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provided a discount under the 340B Program starting January 1, 2026.

We proposed to provide covered entities that choose to submit data to the 340B repository with additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the covered entity previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the covered entity

had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. In instances where the covered entity submits Part D 340B claims data to the repository that is either (1) incomplete or (2) contains invalid data, we may inform the covered entity of such error and request that the covered entity resolve and resubmit the Part D 340B claims data in order to process the submission successfully. We proposed to provide details on the process and timing for covered entities to submit revised data to the 340B repository after the end of the reporting period in the future.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that the 340B repository proposal is operationally manageable. Many commenters appreciated the proposed quarterly timeframes and opportunities for data correction and resubmission. A few commenters recommended CMS allow flexibility for multiple data capture pathways, especially for contract pharmacy networks and rural providers. These commenters recommended CMS provide clear guidance, ample testing time, and financial support for system upgrades. A few commenters stated that some covered entities may need more time than others to set up systems to report data and recommended CMS provide flexibility on the initial implementation timeline for covered entities to develop operations to submit complete data.

Response: We appreciate the commenters for their input and recommendations. We understand that to foster robust data reporting, covered entities will need time to develop a process for collecting the 340B data elements described previously in this final rule and preparing the data in the form and manner prescribed by CMS. Additionally, given the variety in the scope of provider types and organizations that participate in the 340B Program, we recognize that the amount of preparation time will vary. In consideration of these factors and the anticipated launch date for the 340B repository in Fall 2026, we will require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the fields specified by CMS to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. We also note that we are designing the 340B data

collection to be minimally burdensome so that it does not create financial hardship for covered entities. In light of this, we will not provide financial support for system upgrades.

Comment: A commenter questioned how CMS will validate 340B units reported to the repository. A commenter recommended that HRSA expand the 340B Rebate Model Pilot Program to all eligible 340B products and stated that if CMS required participation in the 340B repository, these two programs together would allow for data submitted to HRSA and CMS to be validated across two systems. A commenter recommended that CMS conduct audits of data in the repository, establish ongoing data validation processes, and clarify claims data submission requirements to ensure accuracy and consistency of submitted data.

A few commenters recommended CMS provide covered entities with an opportunity to submit data for 340B claims that were not initially identified or submit corrections to previously submitted data. A commenter recommended that CMS publish annual summaries of corrections made. A commenter recommended that CMS provide a revision period of 30 months to submit revised repository data, stating that the process to certify completeness and accuracy of data creates legal burden. A commenter stated that determining 340B-eligibility can take considerable time and therefore, there may be delays in reporting data to the repository so CMS should consider multiple reconciliation protocols to update rebate reporting.

Response: We appreciate the commenters' feedback and recommendations. As we stated in the CY 2026 PFS proposed rule, we will consider all data elements received by the 340B repository to be associated with Part D 340B claims; that is, the 340B repository will not further verify the 340B status of a claim but rather would serve solely to store these data. We will continue to consider potential data validation processes in the future to help ensure accuracy and completeness of submissions, that is, to help ensure that the data elements received by the 340B repository are associated with Part D 340B claims.

As previously described, we are providing covered entities that choose to submit data to the 340B repository with additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the covered entity previously submitted to the 340B repository in

error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the covered entity had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. In instances where the covered entity submits Part D 340B claims data to the repository that is either (1) incomplete or (2) contains invalid data, we may inform the covered entity of such error and request that the covered entity resolve and resubmit the Part D 340B claims data in order to process the submission successfully. We will provide details on the process and timing for covered entities to submit revised data to the 340B repository after the end of the reporting period in the future.

To the commenter who recommended that HRSA expand the 340B Rebate Model Pilot Program to all eligible 340B products, these comments are out of scope for this final rule because they address another program and topics beyond the scope of the Medicare Part D Drug Inflation Rebate Program.

Comment: A commenter recommended that CMS reconsider the repository (and 340B Rebate Model Pilot Program from HRSA) and instead allow drug manufacturers to operate 340B rebate programs. The commenter explained the potential for efficiency through use of existing technology and evaluation of duplicate discounts across multiple government programs, transparency for all parties to view the same data, and cost savings due to lack of contractors needed to operate the government solutions. Another commenter suggested that CMS explore ways to coordinate data collection and analysis with HRSA to identify 340B-eligible prescriptions.

Response: We appreciate the commenter for their suggestion. At this time, we are adopting our proposal to establish the 340B repository to allow CMS to assess the use of collected data in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program. Comments regarding 340B rebate programs operated by drug manufacturers are out of scope for this final rule because they address other programs and topics beyond the scope of the Medicare Part D Drug Inflation Rebate Program.

After consideration of public comments, we are adopting the policies as proposed.

d. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 428.400 through 428.405)

Section 1860D-14B(a)(1) of the Act requires the Secretary to report to each manufacturer of a Part D rebatable drug the following information not later than 9 months after the end of the applicable period: (1) the amount, if any, of the excess AnMP increase described in section 1860D-14B(b)(1)(A)(ii) of the Act for each Part D rebatable drug, and (2) the rebate amount for each Part D rebatable drug. In compliance with section 1860D-14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug must provide a rebate for each Part D rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1860D-14B(a)(1) of the Act.

In accordance with §§ 428.404 and 428.405, CMS has established a standard method and process to issue Rebate Reports to manufacturers of Part D rebatable drugs and to accept manufacturer rebate payments. CMS has established an online portal, the "Manufacturer Payment Portal" (MPP), administered by a CMS contractor, through which manufacturers will access their Rebate Reports, submit Suggestions of Error, as applicable, and pay rebate amounts due, as described in §§ 428.404 and 428.405. Manufacturers of Part D rebatable drugs should provide points of contact to view the rebate reports described at §§ 428.401 and 428.402, enter and modify banking information, and initiate payments of rebate amounts through the MPP.

We did not make any proposals associated with the method and process to issue Rebate Reports to manufacturers of Part D rebatable drugs and to accept manufacturer rebate payments. We did not receive public comments on these policies.

i. Rebate Reports and Reconciliation (§ 428.401); Deadline and Process for Payment of Rebate Amount (§ 428.405)

As stated in the CY 2025 PFS final rule (89 FR 98264), we codified a multi-step process to provide a manufacturer as set forth in § 428.20 with the rebate information specified in section 1860D-14B(a) of the Act. Specifically, as stated in the CY 2025 PFS final rule (89 FR 98264), we established the information that will be included in a Rebate Report at § 428.401, which includes the NDC(s) identified for the Part D rebatable drug, the total number of units dispensed under Part D for the Part D rebatable drug for the applicable period, and the rebate amount due, among other items specified in § 428.401. Additionally, we established that payment for a rebate amount due must be paid by the 30th day after the date of the receipt of the information containing the rebate amount.

Consistent with the approach specified in section 40 of the revised Medicare Part D Drug Inflation Rebate Guidance, in the CY 2026 PFS proposed rule (90 FR 32644), we proposed adding paragraph (c)(3) at § 428.401 to clarify that CMS will report the manufacturer's rebate amount due as a dollar amount that is rounded to the nearest cent. CMS did not specify an approach to reporting of the rebate amount in the CY 2025 PFS final rule, and we believe it is necessary to provide this information to manufacturers to provide notice of CMS' approach to rounding of the rebate amount. The calculation steps specified in subpart C of part 428 will not include rounded values.

We did not receive public comments on this proposal, and we are finalizing as proposed at § 428.401(c)(3).

Additionally, in the CY 2026 PFS proposed rule (90 FR 32644), we proposed a clarifying edit at § 428.405(a)(1) to specify that the manufacturer must pay the rebate amount due no later than on the 30th calendar day after the date of receipt of the information regarding the rebate amount. The current language specifies that the payment is due "30 calendar days" after the date of receipt of information regarding the rebate amount. CMS does not believe this edit substantively revises the due date.

We did not receive public comments on this proposal, and we are finalizing the revisions as proposed at § 428.405(a)(1).

In the CY 2025 PFS final rule (89 FR 98588), to determine which data elements would be included when CMS reports the rebate amount to the manufacturer, we stated that we considered the statutory requirements outlined in section 1860D-14B(a)(1)(A) through (B) of the Act to determine what information is necessary for manufacturers to review the accuracy of the rebate amount while also protecting proprietary information. As stated in the CY 2025 PFS final rule (89 FR 98588), CMS structured a two-step reporting process to first include a Preliminary Rebate Report to provide an initial notice to manufacturers regarding whether they may owe a rebate amount, followed by the Rebate Report. Further, we proposed and finalized additional data elements within the Preliminary Rebate Reports and the Rebate Reports not listed in statute based on input from public comments (for example, the payment amount benchmark period, the applicable period CPI-U). CMS did not finalize additional elements suggested, such as data at the PDE record level, after weighing whether any such additional information fulfilled CMS' statutory obligation and the potential benefits to manufacturers against the administrative

burdens additional reporting would impose on the agency and operational feasibility. The elements that are set forth at §§ 428.401(b)(1) and (c)(1) satisfy these considerations.

In this final rule, CMS clarifies that certain data elements provided to manufacturers in Preliminary Rebate Reports, Rebate Reports, and reconciled reports of a rebate amount (which may each include the same elements, revised as applicable due to updates in the data), are provided to manufacturers of a Part D rebatable drug in alignment with section 1927(b)(3)(D) of the Act. This section of the Act provides an exception to the confidentiality of information disclosed by manufacturers or wholesalers under section 1927(b)(3) of the Act as the Secretary determines to be necessary to carry out certain sections of the Act, including section 1860D-14B of the Act (that is, the Part D Drug Inflation Rebate Program).

Specifically, CMS anticipates that most data included in Preliminary Rebate Reports, Rebate Reports, reconciled Preliminary Rebate Reports, and reconciled Rebate Reports will not implicate section 1927(b)(3)(D) of the Act, as CMS anticipates that in most cases the party that will receive these reports will be the same party that reported the relevant information. However, we acknowledge that some situations may raise a possibility of disclosure by the Secretary of AMP information, or information derived therefrom, to a party besides the party that reported the information originally; such situations could implicate confidentiality under section 1927(b)(3)(D) of the Act. Such situations may include, but are not necessarily limited to, (1) transfer of a rebatable drug from one manufacturer to another manufacturer, such that the manufacturer identified in the Rebate Report differs from the manufacturer that originally reported certain benchmark pricing information, and (2) information about initial drugs associated with line extensions. In instances where the parties may be different, CMS emphasizes that the data included in a report of the rebate amount is based on CMS' independently performed calculations. Though these calculations rely on information disclosed by manufacturers as inputs, the data reported in a Preliminary Rebate Report and a Rebate Report (or a reconciled version of these reports) will not be identical to the information reported by manufacturers (for example, manufacturers report quarterly AMP values, whereas the benchmark period manufacturer price is an aggregate amount using AMP values across multiple quarters when available). Therefore, reporting such data elements to another manufacturer for purposes of the Medicare Part D Drug Inflation Rebate Program would not violate the confidentiality

requirements in section 1927 of the Act. Additionally, CMS notes that section 1927(b)(3)(D)(i) of the Act provides an exception from the confidentiality provision in section 1927(b)(3)(D) of the Act based on what the "Secretary determines to be necessary to carry out" under 1860D-14B of the Act (among other listed statutory provisions). CMS is applying this exception to the data elements in the Preliminary Rebate Report for the purpose of carrying out the Medicare Part D Drug Inflation Rebate Program.

Second, in the CY 2025 PFS final rule (89 FR 98266), we stated that the purpose of providing additional data elements not explicitly listed in sections 1860D-14B(a)(1)(A) through (B) of the Act (for example, benchmark period manufacturer price, the annual manufacturer price) is based on CMS' assessment of what data elements are necessary for a manufacturer to review the Preliminary Rebate Report for a Suggestion of Error. Providing these data in the Preliminary Rebate Report (and corresponding reports) ensures that (1) manufacturers will be able to submit a Suggestion of Error, thereby promoting accuracy in the implementation of the rebate program, and (2) manufacturers will have advanced notice of a potential rebate amount due.

We did not make any proposals associated with the data elements provided to manufacturers of Part D rebatable drugs in Preliminary Rebate Reports and Rebate Reports (and reconciled versions of these reports); however, we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested that CMS allow State ADAPs to report to CMS directly the ADAP 340B units for CMS to identify 340B direct purchase and 340B rebated units through the Part D inflation rebate report reconciliation process. The commenters stated that some 340B ADAP rebate-eligible drugs are not included in the data reconciled with a manufacturer until after the manufacturer will receive a Rebate Report from CMS because ADAPs submit data to manufacturers up to 12 months after the end of a calendar quarter and manufacturers then are permitted 3 months for reconciliation and payment of rebates to the ADAPs.

Response: We appreciate the commenters' suggestion. As stated in the CY 2025 PFS final rule (89 FR 98264), we codified a multi-step process to provide a manufacturer (as set forth at § 428.20) with a reconciled rebate amount within 12 months and 36 months after the initial Rebate Report is issued for each applicable period. As set forth at § 428.401(d)(1)(ii), the information in the report for a reconciled

rebate amount will include the same data elements as provided in the information provided to the manufacturer of a Part D rebatable drug regarding the preliminary reconciliation of a rebate amount (set forth at § 428.401(d)(1)(i)). This information includes, if applicable, an updated total number of rebatable units, including updates submitted by a PDP or MA-PD plan sponsor and updates to 340B units (as applicable to the dates of service and applicable periods determined at § 428.203(b)(2)(i)(A) and (B)). As discussed in the CY 2025 PFS final rule (89 FR 98264), when considering options for the approach and timing of a reconciliation process, we prioritized, to the extent feasible, completeness and accuracy of the data elements contributing to the calculation of the rebate amount. For the reconciliation process, manufacturers will not be submitting additional information to CMS directly.

ii. Rebate Reports for the Applicable Periods Beginning October 1, 2022, and October 1, 2023 (§ 428.402)

As stated in the CY 2025 PFS final rule (89 FR 97710), we codified at § 428.402 the options afforded to CMS in section 1860D-14B(a)(3) of the Act to delay sending the information required by section 1860D-14B(a)(1) of the Act for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025. Specifically, per § 428.402(c), CMS will issue a Preliminary Rebate Report for each applicable period followed by issuance of the Rebate Report for each applicable period no later than December 31, 2025. Additionally, for the applicable period beginning October 1, 2022, CMS will conduct a single reconciliation 21 months after issuance of the Rebate Report for this applicable period (see § 428.402(c)(1)(ii)). As set forth at § 428.402(c)(2)(ii), for the applicable period beginning October 1, 2023, the rebate amount will be reconciled twice at 9 and 33 months after the Rebate Report is issued for the applicable period. We stated in the CY 2025 PFS proposed rule (89 FR 61983) that this approach aligns claims and payment data run-out with the run-out used during a regular reconciliation cycle. However, CMS finalized the regulatory text specifying the time periods for regular reconciliation cycles at § 428.401(d) with text that provides CMS with operational flexibility as to the exact date the report with the reconciled rebate amount will be provided to each manufacturer of a Part D rebatable drug by including the word "within" prior to the specified date. We proposed to amend §§ 428.402(c)(1)(ii) and (c)(2)(ii) to add the word "within" prior to the specified number of months (for example, 21 months for the applicable period beginning October 1, 2022, and 9 and 33 months for the

applicable period beginning October 1, 2023) to be consistent with the regulatory text and cadence for regular reconciliation cycles, as well as to provide operational flexibility on the timing of the release of the report with the reconciled rebate amount.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 428.402(c)(1)(ii) and (c)(2)(ii).

F. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

As we stated in the CY 2026 PFS proposed rule (90 FR 32645), as of January 1, 2025, the Medicare Shared Savings Program (Shared Savings Program) has 477 accountable care organizations (ACOs) with over 650,000 healthcare providers and organizations providing care to over 11.2 million assigned beneficiaries.[367] Eligible groups of providers and suppliers, such as physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or joining an ACO and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare FFS beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases healthcare spending.

We continue to gain experience with and observe the impact of changes to the Shared Savings Program's quality performance standard and other quality reporting requirements, financial methodology, beneficiary assignment methodology, participation options, and availability of new payment options, among other changes, finalized in recent years through the annual PFS rulemaking process.[368] We proposed changes to the Shared Savings Program regulations to allow for timely improvements to program policies and operations, as described in section III.F. of the CY 2026 PFS proposed rule (90 FR 32645 through 32694).[369] We sought public comments which we summarize and respond to in sections III.F.2. through III.F.9. of this final rule. In section III.F.1.c of this final rule, we provide a summary of the changes we are finalizing to the Shared Savings Program.

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[367] See "Shared Savings Program Fast Facts – As of January 1, 2025", available at https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf.

[368] Refer to the CY 2023 PFS final rule (87 FR 69777 through 69979), CY 2024 PFS final rule (88 FR 79093 through 79232), and CY 2025 PFS final rule (89 FR 98081 through 98213).

[369] In the August 14, 2025, **Federal Register** (90 FR 39155 through 39161), we issued a document that corrects typographical and technical errors in the CY 2026 PFS proposed rule, including corrections to Shared Savings Program content in section III.F and section V.B.5 of the CY 2026 PFS proposed rule.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as "the Affordable Care Act"). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 et seq.) by adding section 1899 of the Act to establish the Medicare Shared Savings Program to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the "November 2011 final rule")). A subsequent update to the program rules appeared in the June 9, 2015, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the "June 2015 final rule")). The final rule entitled "Medicare Program; Medicare Shared Savings Program; Accountable Care

Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations," which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016, **Federal Register** (81 FR 37950) (hereinafter referred to as the "June 2016 final rule"). A final rule, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act," appeared in the November 23, 2018, **Federal Register** (83 FR 59452) (hereinafter referred to as the "November 2018 final rule" or the "CY 2019 PFS final rule"). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018, **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017; final rule (83 FR 67816) (hereinafter referred to as the "December 2018 final rule")). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage

ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020, **Federal Register** (85 FR 19230) (hereinafter referred to as the "March 31, 2020 COVID-19 IFC"), we removed the restriction that prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the public health emergency (PHE) for coronavirus disease 2019 (COVID-19) (85 FR 19267 and 19268).

In the IFC titled "Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program," which was effective on May 8, 2020, and appeared in the May 8, 2020, **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the "May 8, 2020 COVID-19 IFC"), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID-19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID-19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), the CY 2023 PFS final rule (87 FR 69779 and 69780),

the CY 2024 PFS final rule (88 FR 79094 and 79095) and the CY 2025 PFS final rule (89 FR 98082 and 98083). In the CY 2025 PFS final rule (89 FR 98081 through 98213), we finalized changes to Shared Savings Program policies, including to: sunset a requirement under which CMS would terminate an ACO's participation agreement, under certain circumstances, if it failed to maintain at least 5,000 assigned beneficiaries during an agreement period; revise the requirement that newly formed ACOs must agree to allow CMS to share a copy of their application with the Antitrust Agencies; update the definition of primary care services used in beneficiary assignment; revise the Shared Savings Program regulations to broaden a limited exception to the program's voluntary alignment policy; make changes to the quality performance standard and other quality reporting requirements, including to: (1) require Shared Savings Program ACOs to report the Alternative Payment Model (APM) Performance Pathway (APP Plus) quality measure set beginning in performance year 2025 and for subsequent performance years; (2) focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to electronic clinical quality measures (eCQMs) and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) by performance year 2027 and make Merit-based Incentive Payment System clinical quality measures (MIPS CQMs) available in performance years 2025 and 2026; (3) establish a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs; score measures of the Medicare CQM collection type using flat benchmarks for their first two performance periods in MIPS; and (4) extend the eCQM/MIPS CQM reporting incentive for meeting the Shared Savings Program quality performance standard to performance years 2025 and 2026 and extend the eCQM reporting incentive for performance year 2027 and subsequent performance years; allow ACOs receiving advance investment payments to voluntarily terminate from the payment option while remaining in the Shared Savings Program; codify a policy for recouping advance investment payments from ACOs whose participation agreements are terminated by CMS; make modifications to the Shared Savings Program's financial methodology, including to (1) establish a third possible upward adjustment to an ACO's historical benchmark - the health equity benchmark adjustment - based on the number of beneficiaries the ACO serves who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS); (2) establish a calculation methodology to account for the impact of

improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination; (3) establish a methodology for excluding payment amounts for Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes exhibiting significant, anomalous, and highly suspect (SAHS) billing activity during CY 2024 or subsequent calendar years that warrant adjustment; and (4) make technical changes in provisions of the Shared Savings Program regulations on financial calculations, to align and clarify the language used to describe weights applied to the growth in ACO and regional risk scores for each Medicare enrollment type, as part of the calculation for capping ACO and regional risk score growth; and modify beneficiary notification requirements.

In a final rule entitled "Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023," which was effective on October 15, 2024, and appeared in the September 27, 2024, **Federal Register** (89 FR 79152) (hereinafter referred to as the "SAHS billing activity final rule"), we finalized an approach to address the SAHS billing activity CMS identified for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations.

Policies applicable to Shared Savings Program ACOs for purposes of quality reporting for other programs have also continued to evolve based on changes in statute, such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), which established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Provisions

In sections III.F.2. through III.F.9. of this final rule, we summarize and respond to public comments received on the proposed modifications to the Shared Savings Program's policies discussed in section III.F. of the CY 2026 PFS proposed rule (90 FR 32645 through 32694) and any related corrections specified in the CY 2026 PFS proposed rule correction notice (90 FR 39155 through 39161). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of

the proposals discussed in section III.F. of the CY 2026 PFS proposed rule and will not be addressed in this section of this final rule. As a general summary, we are finalizing the following changes to Shared Savings Program policies to:

- Modify requirements for determining an ACO's eligibility for Shared Savings Program participation options, for agreement periods beginning on or after January 1, 2027, to limit participation in a one-sided model to an ACO's first agreement period under the BASIC track's glide path (if eligible), and require ACOs inexperienced with performance-based risk Medicare ACO initiatives (defined at § 425.20) to progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track (subject to the exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both, from participating in the ENHANCED track under the provisions discussed in section III.F.4.b.(2).(b). of this final rule), compared to existing policies (section III.F.2 of this final rule).

- Modify Shared Savings Program eligibility requirements to require ACOs to make certain changes to their ACO participant list when an ACO participant experiences a change of ownership (CHOW) where the surviving Taxpayer Identification Number (TIN) is newly enrolled in the Provider Enrollment, Chain, and Ownership System (PECOS) with no prior Medicare billing claims history, during the performance year and outside of the annual change request cycle, and similarly allow for changes during the performance year to the ACO's Skilled Nursing Facility (SNF) affiliate list if a SNF affiliate undergoes a CHOW resulting in change to the Medicare enrolled TIN (section III.F.3. of this final rule).

- Modify the Shared Savings Program eligibility requirements and financial reconciliation requirements in connection with the statutory requirement that ACOs have at least 5,000 assigned Medicare FFS beneficiaries to:

++ Require ACOs applying to enter a new agreement period to have at least 5,000 assigned beneficiaries in BY3, while allowing the ACO to have fewer than 5,000 assigned beneficiaries in BY1, BY2, or both (section III.F.4.b.(2)(a) of this final rule).

++ Require ACOs that enter a new agreement period with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both to enter the BASIC track (section III.F.4.b.(2).(b). of this final rule).

++ Cap shared savings and shared losses at a lesser amount for ACOs with fewer than 5,000 assigned beneficiaries in any of the three BYs, to help ensure the amounts reflect the ACO's performance in the program rather than normal variation in expenditures (section III.F.4.c.(1). of this final rule).

++ Exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to leverage existing policies that provide certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings (section III.F.4.c.(2). of this final rule).

● Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.F.5. of this final rule).

● Revise the quality performance standard and other quality reporting requirements, including the following (section III.F.6. of this final rule):

++ Revise the definition of a beneficiary eligible for Medicare CQMs at § 425.20 for performance year 2025 and subsequent performance years so that the population identified for reporting within the Medicare CQM collection type would have greater overlap with the beneficiaries that are assignable to an ACO (section III.F.6.b. of this final rule).

++ Remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2026 and revise the terminology used to describe the health equity adjustment and other related terms for performance years 2023 through 2025 (section III.F.6.c. of this final rule).

++ Update the APP Plus quality measure set for Shared Savings Program ACOs including the removal of Quality ID: 487 Screening for Social Drivers of Health (section III.F.6.d. of this final rule).

++ Require CMS-approved survey vendors to administer the CAHPS for MIPS Survey via a web-mail-phone protocol beginning with 2027 (section III.F.6.e. of this final rule).

● Expand the application of the Shared Savings Program quality and finance extreme and uncontrollable circumstances (EUC) policies to an ACO that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years (section III.F.7. of this final rule).

● Revise the Shared Savings Program regulations for performance year 2025 and subsequent performance years to rename the "health equity benchmark adjustment" to the "population adjustment" (section III.F.8. of this final rule).

- Modify the Shared Savings Program quality reporting monitoring requirements at § 425.316 to specify for performance years beginning on or after January 1, 2026, requirements to monitor ACOs for failure to meet both the quality performance standard and the alternative quality performance standard, the latter of which (established in the CY 2023 PFS final rule) was inadvertently omitted from the existing framework. Similarly, modify § 425.224(b)(1)(ii)(A) related to reviewing applications for renewing and re-entering ACOs with a demonstrated pattern of failure to meet both the quality performance standard and the alternative quality performance standard (section III.F.9 of this final rule).

Taken together, the policies we are adopting for the Shared Savings Program in this final rule are anticipated to reduce program spending by $20 million in total through the end of the 10-year period 2026 through 2035, ranging from approximately $590 million lower spending at the 10th percentile to $670 million higher spending at the 90th percentile (as described in the Regulatory Impact Analysis in section VI. of this final rule).

Certain policies, including both existing policies and the new policies adopted in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: changes to the requirements for ACOs' progression to performance-based risk under the program's participation options (described in section III.F.2 of this final rule); potentially applying an alternative loss recoupment limit, in conducting financial reconciliation for each performance year, for an ACO with fewer than 5,000 assigned beneficiaries in any BY, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c of this final rule); excluding ACOs that fall below 5,000 assigned beneficiaries in any BY from being eligible to benefit from the policies providing certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c of this final rule); and mitigating shared losses for an ACO determined to be affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years (described in section III.F.7.c of this final rule). As described in

the Regulatory Impact Analysis in section VI. and elsewhere in this final rule, these changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

2. Shared Savings Program Participation Options Under the BASIC Track

a. Background on Shared Savings Program Participation Options

Section 1899(d) of the Act establishes the general requirements for shared savings payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act specifies that providers of services and suppliers participating in an ACO will continue to receive payments under the original Medicare FFS program under Parts A and B in the same manner as would otherwise be made, and that an ACO is eligible to receive payment for a portion of savings generated for Medicare provided that the ACO meets both the quality performance standards established by the Secretary and achieves savings against its benchmark. Additionally, section 1899(i)(3) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

Since its inception in 2012, the Shared Savings Program has included both one-sided shared savings only models incorporating the statutory payment methodology under section 1899(d) of the Act, and two-sided shared savings and losses models that were also based on the payment methodology under section 1899(d) of the Act but incorporated performance-based risk using the authority under section

1899(i)(3) of the Act to use other payment models.[370] Under the Shared Savings Program regulations at § 425.20, we defined a one-sided model to mean a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under 42 CFR part 425 subpart G. At § 425.20, we defined a two-sided model to mean a model under which an ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G. Subpart G of the program's regulations includes provisions on the calculation of shared savings and losses (as applicable) under the program's tracks, or levels of participation, among other policies.

At § 425.600, we describe the options for an ACO's selection of a risk model. This section includes the criteria used by CMS to determine an ACO's eligibility to participate under the program's tracks, or levels of participation, as well as limitations on the amount of time an ACO may participate under a one-sided model, options and requirements for an ACO to participate under a two-sided model, and provisions governing the progression from a one-sided model to higher levels of risk and potential reward under a two-sided model (as applicable).

Over time, we have modified the available financial models under the Shared Savings Program, and approaches to determining an ACO's eligibility to participate under these financial models, which we refer to as the ACO's participation options. For additional information on the changes to the Shared Savings Program's available financial models, including finalization of the existing policies and background on earlier requirements, we refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69805 through 69821).

As finalized with the December 2018 final rule (83 FR 67831 through 67841), for agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs enter into an agreement period of not less than 5 years under one of two tracks of the Shared Savings Program, either the BASIC track (see §§ 425.600(a)(4) and 425.605) or the ENHANCED track (see §§ 425.600(a)(3) and 425.610). The BASIC track includes a glide path from one-sided model Levels A and B[371] to incrementally higher levels

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[370] For additional background, we refer readers to the CY 2023 PFS final rule (87 FR 69805 and 69806) for a summary of changes to the program's financial models, or "tracks," over time.

[371] For details on the Level A financial model, see §§ 425.600(a)(4)(i)(A)(*1*) and 425.605(d)(1)(i). For details on the Level B financial model see §§ 425.600(a)(4)(i)(A)(*2*) and 425.605(d)(1)(ii).

of performance-based risk under Levels C, D, and E.[372] The ENHANCED track offers the highest level of risk and potential reward under the Shared Savings Program. Level E of the BASIC track and the ENHANCED track each qualify as an Advanced APM under the Quality Payment Program.[373]

In rulemaking following the December 2018 final rule, we modified the approach for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track, along with the number of performance years an ACO may remain under a one-sided model of the BASIC track's glide path.[374] As finalized with the CY 2023 PFS final rule (87 FR 69805 through 69821), for agreement periods beginning on or after January 1, 2024, § 425.600(g) specifies the criteria CMS uses to determine an ACO's eligibility to enter an agreement period under the BASIC track's glide path, Level E of the BASIC track, or the ENHANCED track. Under these policies, CMS determines an ACO's eligibility for participation options in the BASIC track and ENHANCED track based on the ACO's experience and its ACO participants' experience with the Shared Savings Program and other performance-based risk Medicare ACO initiatives.[375] In accordance with § 425.600(g), we use the following approach:

- If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20),[376] the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward (Levels A through E), or the ENHANCED track. In accordance with § 425.600(g)(1)(i) through (iii), an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of two agreement periods:

++ An ACO that enters an agreement under the BASIC track's glide path at either Level A or Level B is deemed to have completed one agreement under the BASIC track's glide path and is only

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[372] For details on the Level C financial model, see §§ 425.600(a)(4)(i)(A)(*3*) and 425.605(d)(1)(iii). For details on the Level D financial model, see §§ 425.600(a)(4)(i)(A)(*4*) and 425.605(d)(1)(iv). For details on the Level E financial model, see §§ 425.600(a)(4)(i)(A)(*5*) and 425.605(d)(1)(v).

[373] For related information, on Advanced APM status under the Quality Payment Program for each track / level, see the December 2018 final rule, Table 3 "Comparison of Risk and Reward Under BASIC Track and ENHANCED Track", and table notes at 83 FR 67852 and 67853.

[374] We refer readers to discussions in earlier rulemaking, including: December 2018 final rule (83 FR 67863 through 67922); May 8, 2020 COVID-19 IFC (85 FR 27575 and 27576) and CY 2021 PFS final rule (85 FR 84767 through 84769); Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (86 FR 45502 through 45506); and CY 2023 PFS final rule (87 FR 69805 through 69821).

[375] See the definitions of "experienced with performance-based risk Medicare ACO initiatives," "inexperienced with performance-based risk Medicare ACO initiatives," and "performance-based risk Medicare ACO initiative" under § 425.20.

[376] In accordance with § 425.20 "inexperienced with performance-based risk Medicare ACO initiatives" means an ACO that CMS determines meets all of the following: (1) the ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined at § 425.20, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model at § 425.200(e); and (2) less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model at § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years. For brevity, we sometimes refer to such ACOs as "inexperienced with performance-based risk" or "inexperienced with risk."

eligible to enter a second agreement under the BASIC track's glide path if the ACO continues to meet the definition of inexperienced with performance-based risk Medicare ACO initiatives and satisfies either of the following: (A) the ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path only one time; or (B) for a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path only one time.

++ An ACO that is determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track.

- If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20), the ACO may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track.

Section 425.600(a)(4)(i)(C) specifies glide path progression for agreement periods beginning on or after January 1, 2024. Under these requirements, an ACO eligible to enter the BASIC track's glide path may elect to enter its agreement period at any of the levels of risk and potential reward available under Levels A through E. An ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track, except in the following circumstances: (1) the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided at § 425.226(a)(2)(i); (2) the ACO elects to maintain its level of participation as provided at § 425.600(a)(4)(i)(C)(*3*);[377] or (3) the ACO elected to participate under a one-sided model, but is determined to be experienced with performance-based risk Medicare ACO initiatives and will be automatically advanced to Level E within the BASIC track at the start of the next performance year and

[377] In accordance with § 425.600(a)(4)(i)(C)(*3*), a new ACO (not a renewing ACO or re-entering ACO as defined at § 425.20) participating in its first agreement period under the BASIC track that enters the glide path at Level A may elect to remain under Level A for all subsequent performance years of the agreement period. As described in the CY 2023 PFS final rule (87 FR 69809), an ACO must make this election prior to its automatic advancement to Level B for performance year 2 of its agreement period under the BASIC track's glide path.

will remain in Level E for all subsequent performance years of the agreement period, in accordance with § 425.600(h)(2)(i).[378]

Under our existing policies, new ACOs inexperienced with performance-based risk Medicare ACO initiatives may participate in a BASIC track one-sided model for up to 7 performance years before being required to transition to performance-based risk. For example, an eligible ACO may enter a first BASIC track agreement period in the glide path and elect to remain under Level A for all 5 performance years of this agreement period. If the ACO is eligible to enter a second BASIC track agreement period in the glide path and enters at Level A for its first performance year, the ACO would be automatically advanced to Level B in its second performance year, respectively its sixth and seventh cumulative performance years under a one-sided model. The ACO would participate under performance-based risk for the third and subsequent performance years of its second agreement period under the BASIC track, either by being automatically advanced to Level C, D and E for each of the 3 remaining performance years of its second agreement period under the glide path, or electing to advance more rapidly to higher levels of risk and reward along the glide path.

ACOs that initially elect to remain in Level A of the BASIC track for all 5 performance years for their first agreement period under the BASIC track have the option to subsequently elect to transition to performance-based risk during this agreement period in accordance with § 425.226(a)(2)(i) and § 425.600(a)(4)(i)(C)(*3*)(*iii*), and (a)(4)(i)(C)(*4*) to (*6*). For example, an ACO inexperienced with performance-based risk Medicare ACO initiatives that enters an agreement period under the BASIC track at Level A and elects to maintain participation at Level A for the second and subsequent performance years of this agreement period may subsequently elect to advance to a two-sided model along the BASIC track's glide path (Level C, D or E) for performance year 3, 4 or 5 of this agreement period. In such a case, in accordance with § 425.600(a)(4)(i)(C)(*6*), when an ACO elects to transition to a higher level of risk and reward available under the BASIC track's glide path, the ACO would be automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available. Further, in progressing to

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[378] We refer readers to the CY 2023 PFS final rule (87 FR 69811 and 69812), in which we finalized the approach to monitoring of risk experience for agreement periods under Level A of the BASIC track, for performance years beginning on or after January 1, 2024, for a detailed explanation and examples of the approach.

performance-based risk in the BASIC track's glide path, the ACO would be considered experienced with performance-based risk Medicare ACO initiatives for purposes of determining the ACO's participation options for a future agreement period, and therefore eligible to enter either the BASIC track Level E for all performance years or the ENHANCED track in accordance with § 425.600(g)(2).

CMS accepts applications for ACOs to participate in the Shared Savings Program annually. Applicant ACOs are required to make a track selection when submitting their application, which is reviewed by CMS to determine the ACO's eligibility for the selected option.[379] During the annual change request cycle, for ACOs currently participating in the program, ACOs participating in the BASIC track's glide path have the opportunity to submit participation options change requests, in connection with their level of participation, among other change requests, prior to the start of the next performance year in the program. For instance, ACOs participating in the BASIC track's glide path may elect to remain in Level A (if participation in Level A was previously elected), or to advance to higher levels of risk and reward along the glide path.[380] The timing of the annual application cycle and change request cycle typically coincide, and span a period from Spring through Fall in advance of the start of the upcoming performance year beginning on January 1st.[381] During the application and change request cycles, CMS communicates information about an ACO's experience with performance-based risk Medicare ACO initiatives, and track / level eligibility, among other information, at standardized intervals, to applicant ACOs and currently participating ACOs.

b. Considerations for Timing of ACOs' Progression to Performance-Based Risk in the Shared Savings Program

In the CY 2026 PFS proposed rule (see 90 FR 32650 and 32651), we explained our belief, including as described in earlier rulemaking, that financial models under which ACOs bear a degree of financial risk have potential to induce more meaningful systematic change in providers' and suppliers' behavior towards meeting the Shared Savings Program's goals, compared to one-sided models (see for

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[379] See Medicare Shared Savings Program, Application Reference Manual (April 2025, version 7), available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/ssp-application-reference-manual.pdf.
[380] See Medicare Shared Savings Program, Managing Program Participation Guidance (April 2025, version 2), available at https://www.cms.gov/files/document/managing-program-participation-guidance.pdf.
[381] For resources and information on the Shared Savings Program application and change request cycles, refer to the Shared Savings Program website at https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos (including the Application Types & Timelines webpage, and Application Toolkit webpage).

example, 76 FR 67904 through 67909, 80 FR 32758 through 32760, and 83 FR 67967 through 67968). As described in the CY 2026 PFS proposed rule (90 FR 32648 through 32650), our policies on the amount of time an ACO can participate under a one-sided model of the Shared Savings Program, and progression to two-sided risk, have varied over time, including as a result of changes finalized with the CY 2023 PFS final rule (see 87 FR 69805 through 69818). In the CY 2023 PFS final rule (87 FR 69808), we explained our ongoing consideration for how long ACOs should be allowed to participate under a one-sided model. In explaining what has contributed to this consideration, we identified the importance of balancing our goal of driving the greatest possible shift to high-value care delivery, which we believe may be incentivized most effectively under a two-sided model, with a concern that requiring ACOs to take on too much downside risk too quickly may disincentivize program participation and reduce the program's potential to positively affect the quality and cost of care furnished to beneficiaries. As described in the CY 2023 PFS final rule, a number of factors informed our proposal and decision to finalize the current approach that allows eligible ACOs to participate for a 5-year agreement period under Level A of the BASIC track with the opportunity to enter a second agreement period under the BASIC track's glide path beginning under a one-sided model. In the CY 2026 PFS proposed rule, we summarized the considerations discussed in the CY 2023 PFS final rule.

In the CY 2023 PFS final rule (see 87 FR 69806 and 69807), we provided background on comments summarized in the December 2018 final rule, which finalized our proposal to limit ACOs to two performance years under a one-sided model (or three performance years for eligible low revenue ACOs).[382] We explained that most commenters on that proposal recommended that CMS extend the time any ACO can participate in a one-sided model to 3 performance years, as opposed to the 2 performance years proposed for ACOs eligible to participate under the BASIC track with participation agreements beginning on or after January 1, 2020 that do not qualify for a third year under the one-sided model under the exception at § 425.600(a)(4)(i)(B)(*2*)(*ii*), stating that it takes longer than 2 performance years to implement meaningful changes in a healthcare delivery model and among healthcare provider and patient

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[382] See § 425.600(a)(4)(i)(B)(*2*)(*i*)-(*ii*) for provisions on automatic advancement along the BASIC track's glide path. Note that ACOs with an agreement period beginning on July 1, 2019, could participate under a one-sided model for up to 3 performance years under the exception to automatic advancement along the BASIC track's glide path in accordance with § 425.600(a)(4)(i)(B)(*2*)(*i*), or for four performance years under the exception for eligible low revenue ACOs in accordance with § 425.600(a)(4)(i)(B)(*2*)(*ii*).

populations. Other commenters believed that the progression to two-sided risk that we proposed and ultimately finalized was far too aggressive and would deter participation. These commenters generally suggested allowing for 4 or 5 performance years (or a full agreement period) under a one-sided model. Some commenters suggested that rural ACOs should be allowed at least two, 5-year agreement periods under a one-sided model (83 FR 67847).

In the CY 2023 PFS final rule (87 FR 69807 and 69808), we described participation trends for PY 2022 and explained that while many ACOs had agreed to participate under a two-sided model, not all ACOs appeared to be ready to take on performance-based risk. In particular, we described our experience with policies finalized in connection with the PHE for COVID-19, in which ACOs participating in the BASIC track's glide path could forgo automatic advancement and "freeze" their participation for PY 2021 and PY 2022 at their PY 2020 and PY 2021 levels, respectively.[383] We observed that when given the opportunity to freeze at the ACO's current BASIC track level of the glide path, most eligible ACOs under a one-sided model (Level A or Level B) chose to remain in a one-sided model. More generally, we explained that although we continued to believe there are stronger incentives for increased efficiency when ACOs are in a two-sided risk track, ACOs had continued to report that they were constrained by the participation options finalized with the December 2018 final rule, and needed more time to invest in infrastructure and redesigned care processes for high quality and efficient healthcare service delivery before transitioning to performance-based risk. See 87 FR 69808.

We noted our determination that allowing a maximum of 7 years under the one-sided model, as finalized in the CY 2023 PFS final rule, would strike a more appropriate balance within the structure of 5 performance year agreement periods, than only allowing for 2 years under a one-sided model. See 87 FR 46114; see also 87 FR 69809. We also noted that giving ACOs longer than 7 years or potentially unlimited time under a one-sided model would dilute the program's ability to meaningfully influence expenditures and quality through the incentives provided by ACO risk assumption. Moreover, we explained that the approach that would extend the time an eligible ACO could participate under a one-sided model to 7 years would allow ACOs more time to make investments in care improvement and to

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[383] The PHE for COVID-19 was in effect starting in January 2020, and ongoing at the time of the CY 2023 PFS rulemaking during 2022 and expired on May 11, 2023. See for example, U.S. Department of Health and Human Services website, COVID-19 Public Health Emergency webpage, available at https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.

capitalize on these investments, while still working to lower costs and improve the quality of care for their assigned beneficiaries. 87 FR 69809. We also recognized that ACOs are best able to select their participation options to meet the needs of their organizations, including when to time their transition to performance-based risk, including within an agreement period. *Id.* We also explained our intention with these changes was to provide ACOs with a more gradual "on-ramp" to taking on two-sided risk and to allow them the flexibility to best ensure their readiness to take on two-sided risk, and our belief that the approach would encourage more ACOs to form and join the program, as well as encourage currently participating ACOs to remain in the program. See 87 FR 69812, and 69816.

In the CY 2023 PFS final rule, we also recognized differing potential barriers to program participation by low revenue ACOs, and high spending ACOs, among other ACOs with particular characteristics or compositions. For instance, we recognized the importance of finalizing the participation option under which an eligible ACO may stay in a one-sided model of the BASIC track for the full 5-year agreement period for growing participation in the Shared Savings Program by eligible ACOs serving higher spending populations, particularly low revenue, physician-led ACOs. See 87 FR 70195. In combination with the expanded time under a one-sided model, policies finalized with the CY 2023 PFS final rule to allow the option for eligible new, low revenue ACOs inexperienced with risk to receive advance investment payments (see § 425.630), and expanded opportunities for certain low revenue ACOs participating in the BASIC track to share in savings even if they do not meet the MSR (see § 425.605(h)), were designed to support program participation by low revenue ACOs. See 87 FR 70195. Additionally, in the CY 2023 PFS final rule (87 FR 70192), we explained that in combination with modifications to the benchmarking methodology to reduce the impact of the negative regional adjustment also being finalized in that rule, offering eligible ACOs a shared savings-only BASIC track participation option for a full 5-year agreement period, was expected to significantly re-engage participation for ACOs serving higher cost beneficiaries. We also explained our belief that flexibility with respect to the timeline for progression to two-sided risk would be important in the Shared Savings Program to encourage small, rural, safety-net providers to form ACOs or to join larger, more urban practices to share resources, which among other factors could help provide high need beneficiaries served by small, rural, safety-net providers with the resources to better coordinate their care and improve outcomes. See 87 FR 69809, and 69813.

As discussed in the CY 2026 PFS proposed rule (90 FR 32652), CMS has announced a vision to Make America Healthy Again.[384] Relatedly, the Innovation Center announced a strategy to focus on testing models that transform the U.S. health system into one that builds healthier lives through prevention, individual empowerment, and choice and competition, under which people achieve their health goals and the providers caring for them are directly accountable for their health outcomes and the costs of their care.[385] This strategy includes, among other measures to protect Federal taxpayers, requiring all models to have downside financial risk and requiring providers to assume some of the financial risk. Similarly, with the Shared Savings Program, we are examining approaches to encourage ACO participation under two-sided models.

In the CY 2026 PFS proposed rule (90 FR 32652), we specified that in light of CMS' current vision and strategic direction, we are revisiting Shared Savings Program policies on the amount of time an ACO can remain under a one-sided model, and the progression to performance-based risk, and in particular the current policy that allows ACOs to participate for up to 7 performance years under a one-sided model. Specifically, we stated that we are considering the effectiveness of the current requirements for determining an ACO's participation options, finalized with the December 2018 final rule, and modified through subsequent rulemaking, including the CY 2023 PFS final rule, in achieving a balance between encouraging transition to two-sided risk and a concern that requiring ACOs to take on too much downside risk too quickly may disincentivize program participation. In a discussion in the CY 2026 PFS proposed rule (90 FR 32652 through 32655), we described more recent trends in ACO participation in the Shared Savings Program (including as a result of changes to program requirements through rulemaking) and ACO financial performance, which inform our consideration of our current policies on ACOs' progression to performance-based risk under the Shared Savings Program. This discussion focuses on Shared Savings Program participation trends in general between PY 2018 and PY 2025; participation trends among new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives, and ACOs serving medically complex, high-cost populations, for which we have finalized

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[384] See CMS Press Release, "Dr. Mehmet Oz Shares Vision for CMS", April 10, 2025, available at https://www.cms.gov/newsroom/press-releases/dr-mehmet-oz-shares-vision-cms (explaining CMS will work to modernize Medicare, the Marketplaces and Medicaid, so Americans get the care that they want, need, and deserve, including by holding healthcare providers accountable for health outcomes).

[385] See Sutton, Abe, White Paper "CMS Innovation Center Strategy to Make America Healthy Again", May 13, 2025, available at https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again.

policies to facilitate program participation through CY 2023, 2024, and 2025 PFS rulemaking; our experience with the timing of ACO progression to performance-based risk under participation options that allow an eligible ACO to participate for up to 7 performance years under a one-sided model; and financial performance trends for recent performance years, among ACOs transitioning from one-sided to two-sided levels of the BASIC track, or remaining under the BASIC track's two-sided model levels. In this final rule, we restate this discussion from the CY 2026 PFS proposed rule, with certain updated statistics, as noted.

The redesign of participation options with the December 2018 final rule greatly increased ACO participation in two-sided models.[386] For PY 2018, 82 percent of ACOs were participating under a one-sided model, and 18 percent of ACOs were participating under a two-sided model.[387] For PY 2025, 29 percent of ACOs are participating under a one-sided model, and 71 percent of ACOs are participating under a two-sided model.[388] With respect to recent trends, Table B-G1 shows the number of ACOs participating in the BASIC track (by Level) and ENHANCED track for PYs 2022 through 2025.[389] As shown in Table B-G1, participation in one-sided models is lower in PY 2025 (29 percent of ACOs) compared to PY 2022 (41 percent of ACOs), and PY 2023 and PY 2024 (33 percent of ACOs for each PY). Further, from program participation for PYs 2022 through 2025, we have observed that when ACOs participate under two-sided risk they opt for higher levels of risk and reward. Very few ACOs are participating under Levels C or D of the BASIC track's glide path, compared to participation in Level E of the BASIC track or the ENHANCED track. Among ACOs participating under two-sided risk, more ACOs are participating under the highest level of risk and potential reward offered by the ENHANCED track than in Levels C, D and E of the BASIC track combined.

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[386] For data on ACO participation in the Shared Savings Program by track / level and performance year, see Shared Savings Program "Fast Facts" available through the Medicare Shared Savings Program website, Program Data webpage at https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/data (including the "Fast Facts Archives" (zip file), available at https://www.cms.gov/media/638196). See also, Data.CMS.gov, Medicare Shared Savings Program, Accountable Care Organizations, Public Use File (by performance year), available at https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations. We note that some observations described in the CY 2026 PFS proposed rule (90 FR 32648 through 32659) as restated in this section of this final rule, particularly for PY 2025 data, are based on internal analysis.

[387] See "Medicare Shared Savings Program Fast Facts (January 2018)", within "Fast Facts Archives", available at https://www.cms.gov/media/638196.

[388] See "Shared Savings Program Fast Facts – As of January 1, 2025", available at https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf.

[389] See "Shared Savings Program Fast Facts – As of January 1, 2025", available at https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf. See also, "Shared Savings Program Fast Facts –As of January 1, 2022," "Shared Savings Program Fast Facts –As of January 1, 2023," and "Shared Savings Program Fast Facts – As of January 1, 2024", within "Fast Facts Archives", available at https://www.cms.gov/media/638196.

TABLE B-G1: COUNT OF ACOs PARTICIPATING IN BASIC TRACK LEVELS AND ENHANCED TRACK FOR PYs 2022 THROUGH 2025

Performance Year	Total	BASIC Track			ENHANCED Track
		Levels A and B	Levels C and D	Level E	
PY 2022	483	199 (41%)	40 (8%)	98 (21%)	146 (30%)
PY 2023	456	151 (33%)	19 (4%)	125 (28%)	161 (35%)
PY 2024	480	159 (33%)	10 (2%)	104 (22%)	207 (43%)
PY 2025	477	137 (29%)	5 (1%)	81 (17%)	254 (53%)

Shared Savings Program participation with the two most recent start dates shows that nearly one-half of new ACOs are entering a one-sided model of the BASIC track, while the vast majority of ACOs continuing their participation in the program are participating under a two-sided model. Among the 140 ACOs entering a new agreement period for the January 1, 2024, start date, 51.6 percent (or 31 of 60) of ACOs participating in their first agreement period entered the BASIC track at Level A, while 2.5 percent (or 2 of 80) of ACOs participating in their second or subsequent agreement period entered the BASIC track at Level A. Among the 229 ACOs entering a new agreement period for the January 1, 2025 start date, 45.9 percent (or 17 of 37) of ACOs participating in their first agreement period entered the BASIC track at Level A or B, while 17.7 percent (or 34 of 192) of ACOs participating in their second or subsequent agreement period entered the BASIC track at Level A.

We have gained experience with ACOs' participation under changes to the Shared Savings Program policies more recently finalized with CY 2023, 2024 and 2025 PFS rulemakings, which include policies to encourage participation by new, low revenue ACOs, such as through the availability of a payment option for eligible ACOs to receive advance investment payments, and ACOs serving medically complex, high-cost patient populations, such as through changes to the program's benchmarking methodology. Our initial experience with ACOs entering agreement periods beginning on January 1, 2024 and January 1, 2025, offers insight into participation among such ACOs.

For agreement periods beginning on January 1, 2024, and subsequent years, eligible new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives may receive advance shared savings payments in the form of advance investment payments designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program (see 87 FR 69782 through 69806). To be eligible to receive advance investment payments for the first two performance years of the ACO's agreement period, the ACO must enter the program under BASIC track Level A and remain under

a one-sided model level of the BASIC track's glide path (Level A or B) for its second performance year, among other requirements specified at § 425.630(b). Among the new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives recently entering a first agreement period in the Shared Savings Program under a one-sided model, 19 of 21 of these new, low revenue ACOs inexperienced with performance-based risk entering an agreement period beginning on January 1, 2024 opted to receive advance investment payments for at least one performance year, while 10 of 12 of these new, low revenue ACOs inexperienced with performance-based risk entering an agreement period beginning on January 1, 2025 are receiving advance investment payments for PY 2025.[390]

Further, through recent rulemaking, we have refined the Shared Savings Program's financial benchmarking methodology to support participation by ACOs serving medically complex, high-cost populations. For instance, with the CY 2025 PFS final rule (89 FR 98155 through 98166), we established an approach applicable for agreement periods beginning on January 1, 2025, and in subsequent years, under which we adjust an ACO's historical benchmark based on the highest of three positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or health equity benchmark adjustment, in accordance with § 425.652(a)(8)(ii). As we explained in the CY 2025 PFS final rule (see 89 FR 98157), the health equity benchmark adjustment (HEBA), was designed to encourage new participation from ACOs serving medically complex, high-cost populations that are receiving lower regional adjustments or lower prior savings adjustments or receiving neither adjustment. As described in the CY 2025 PFS final rule (89 FR 98523 and 98524), increased program participation by these ACOs as a result of these benchmark changes are expected to generate $260 million greater net savings for Medicare over 10 years.

Based on early experience with program participation for the January 1, 2025 agreement period start date, the HEBA (which we are renaming the "population adjustment," as described in section III.F.8 of this final rule) is anticipated to provide an upward adjustment to ACO historical benchmarks for 16 of 229 ACOs that began a new agreement period for the 2025 start date (which includes new, renewing and re-entering ACOs and is approximately 7 percent of ACOs beginning a new agreement period with a

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[390] See Medicare Shared Savings Program, Accountable Care Organizations, Public Use Files, for PY 2024 and PY 2025, available at https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations. We note that one ACO that began receiving advance investment payments in PY 2024 is no longer receiving these payments in PY 2025.

January 1, 2025 start date). From an internal analysis of PY 2025 final historical benchmarks for ACOs entering an agreement period beginning on January 1, 2025, we estimate that among the 16 ACOs that are anticipated to receive a HEBA to their historical benchmark, 8 are new ACOs participating in their first agreement period and would otherwise not have received a positive adjustment to the benchmark, 5 are in a one-sided model, and 3 are in a two-sided model.[391] While we are still gaining experience with the impact of the HEBA on ACO benchmarks and ACO participation, these findings suggest that the HEBA may incentivize participation in the Shared Savings Program from ACOs serving high spending and high-risk populations, including encouraging participation in two-sided models.

More generally, we considered participation trends among ACOs that are higher spending compared to their regional service area, which would have a negative regional adjustment value, and ACOs with lower spending compared to their regional service area, which would have a positive regional adjustment value (see §§ 425.601(f)(5) and 425.656(e)(5)). Based on internal analysis, among both groups of ACOs—higher spending or lower spending compared to their regional service area—entering the program for an initial agreement period with the 2022, 2023, 2024 or 2025 start date, either an equal number of ACOs, or more ACOs, entered two-sided models compared to one-sided models. We also observe that the number of ACOs with higher spending compared to their regional service area that are entering the program for an initial agreement period has generally increased with recent start dates, with 6 of such ACOs entering in 2022, 9 of such ACOs entering in 2023, 17 of such ACOs entering in 2024, and approximately 18 of such ACOs entering in 2025.[392] These trends suggest that the policies adopted in CY 2023, 2024, and 2025 PFS rulemaking cycles, applicable for the January 1, 2024 and January 1, 2025 start dates, are encouraging participation from ACOs serving high spending and high risk populations. As a more general consideration, we continue to recognize there are ACOs that may need time to gain experience with the Shared Savings Program by participating in a one-sided model prior to transitioning to two-sided risk, which may be indicated by entry of some higher spending ACOs in the Shared Savings Program under a one-sided model for their first agreement period.

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[391] Final calculations for the population adjustment include use of the ACO's PY 2025 assigned beneficiary population, in accordance with § 425.662(b)(4), determined at the time of financial reconciliation. Following the publication of the CY 2026 PFS proposed rule, we have updated the values referenced in this discussion, which tracks discussion in the proposed rule (90 FR 32653), using more updated data.

[392] Figures are restated from the CY 2026 PFS proposed rule (90 FR 32654), with an update to the PY 2024 and PY 2025 values based on more recently available data.

Additionally, the experience of new ACOs entering the program with July 1, 2019 or January 1, 2020 agreement period start dates provides insight into participation options in which ACOs are allowed to participate for a first agreement period in the BASIC track's glide path under a one-sided model and renew their participation agreements to continue their participation in the glide path.[393] We analyzed program participation by ACOs that entered a first agreement period beginning on July 1, 2019 or January 1, 2020,[394] and renewed to continue their participation in the Shared Savings Program for a second or subsequent agreement period, for trends in whether ACOs have chosen to enter and remain in a one-sided model (if eligible) or progress to performance-based risk. For July 1, 2019 starters, our observations span a period of 7 performance years (the 6-month performance year from July 1, 2019 through December 31, 2024, and PYs 2020 through 2025). For 2020 starters, our observations span a period of 6 performance years (PYs 2020 through 2025). As shown in Table B-G2, many ACOs appear prepared to participate under two-sided risk after 5 or fewer years under a one-sided model. Approximately 16 percent (or 4 of 25) of July 1, 2019 starters, and 10.5 percent (or 2 of 19) of 2020 starters chose to enter and remain under one-sided for their first agreement period and upon renewal in a second agreement period of the BASIC track's glide path, while the vast majority of ACOs elected to participate under performance-based risk either during their first agreement period or upon renewal.

TABLE B-G2: PARTICIPATION AS OF PY 2025 FOR ACOs THAT ENTERED A FIRST AGREEMENT PERIOD BEGINNING ON EITHER JULY 1, 2019 OR JANUARY 1, 2020 AND RENEWED TO CONTINUE PARTICIPATION IN THE SHARED SAVINGS PROGRAM

Track / Level for ACO's First Agreement Period and as of PY 2025	New ACOs for 7/1/2019 Start Date	New ACOs for 1/1/2020 Start Date
Participated in one-sided model of the BASIC track for 1st agreement period; entered 2nd agreement period in the BASIC track's glide path at Level A	4 (16.0%)	2 (10.5%)
Participated in one-sided model of the BASIC track for 1st agreement period; entered 2nd agreement period under two-sided risk at renewal	9 (36.0%)	9 (47.4%)
Entered a one-sided model of the BASIC track at the start of its 1st agreement period and progressed to a two-sided model of the BASIC track during 1st agreement period	6 (24.0%)	2 (10.5%)
Participated in two-sided model for 1st agreement period; continued participation in two-sided model for 2nd agreement period	6 (24.0%)	6 (31.6%)
Total	25 (100%)	19 (100%)

Note: The total number of ACOs excludes ACOs with a participation agreement effective termination date prior to January 1, 2025: 19 ACOs with a July 1, 2019 start date of which 13 ACOs were participating in a one-sided model; and 17 ACOs with a 2020 start date of which 10 ACOs were participating under a one-sided model.

[393] Eligible ACOs that participated under the BASIC track's glide path for an agreement period beginning on July 1, 2019, or January 1, 2020, and entered in Level A or Level B, were allowed to elect to continue their participation in a one-sided model for the duration of their agreement period, as a result of a series of policy changes. See § 425.600(a)(4)(i)(B)(*1*), (a)(4)(i)(B)(*2*)(*i*), (a)(4)(i)(B)(*2*)(*iii*)-(*iv*) and (a)(4)(i)(B)(*2*)(*vi*). If eligible, these ACOs could enter a second agreement period under the BASIC track's glide path in accordance with § 425.600(g)(1).

[394] The agreement period from July 1, 2019, through December 31, 2024, spanned 5 years and 6 months, across 6 performance years, in accordance with § 425.200(b)(4)(ii) and (c)(3). The agreement period from January 1, 2020, through December 31, 2024, spanned 5 years, in accordance with § 425.200(b)(5).

As described in the Regulatory Impact Analysis in the CY 2026 PFS proposed rule (see 90 FR 32815), we analyzed the financial performance of groups of ACOs that participated in both PYs 2022 and 2023. Cohorts were assembled based on the track/level of participation of the ACOs in PY 2022 and PY 2023. This analysis shows the highest rates of average net savings among the following groups: (1) ACOs remaining in two-sided models of the BASIC track (Levels C, D or E) over the 2-year period; and (2) ACOs moving from a one-sided model of the BASIC track (Level A or B) to a two-sided model of the BASIC track (Level C, D or E) over PY 2022 to PY 2023. These cohorts also demonstrated the lowest average unadjusted per capita spending growth rates over this 2-year period. These findings suggest that ACOs transitioning to or remaining in two-sided model levels of the BASIC track outperform ACOs remaining in one-sided models of the BASIC track.

To follow is a summary of the key points from our observations previously described in the CY 2026 PFS proposed rule and restated in this section of this final rule. Based on early experience with ACO participation under policies applicable with agreement periods beginning on January 1, 2024, or January 1, 2025, and subsequent years, the option for ACOs to enter a one-sided model for a first agreement period in the BASIC track appears to be an important pathway for attracting new ACOs to enter the Shared Savings Program, including new, low revenue ACOs, particularly in combination with the option to receive advance investment payments, and ACOs serving higher spending populations, particularly in combination with the benchmarking methodology applicable for agreement periods beginning on January 1, 2025, and subsequent years, under which an ACO may receive an upward adjustment to its benchmark through the application of the HEBA. From participation trends of ACOs entering the Shared Savings Program for a first agreement period beginning on July 1, 2019 or January 1, 2020, few ACOs choose to remain under a one-sided model beyond an initial agreement period under the BASIC track's glide path, and many more ACOs were prepared to participate under a two-sided model either during their first agreement period or upon renewal. Further, based on participation data from PYs 2022 through 2025, ACOs are tending to enter the program's two-sided models under the highest levels of risk and potential reward, under Level E of the BASIC track or the ENHANCED track. Additionally, ACOs transitioning from one-sided to two-sided levels of the BASIC track, or remaining under the

BASIC track's two-sided model levels, are anticipated to generate higher levels of average net savings compared to ACOs that remain in a one-sided model of the BASIC track, based on internal analysis of PY 2022 and PY 2023 financial performance.

c. Limiting Participation in a One-Sided Model to an ACO's First Agreement Period Under the BASIC Track's Glide Path

As discussed in the CY 2026 PFS proposed rule (90 FR 32655 through 32659), we believe that an approach under which we limit the amount of time an ACO can remain under a one-sided model of the Shared Savings Program and thereby encourage ACOs to transition to performance-based risk, would align with our current strategic direction, as part of achieving CMS' vision to Make America Healthy Again. We explained that, in light of the findings we described from our experience with ACOs' participation in the Shared Savings Program under agreement periods beginning on or after July 1, 2019 through January 1, 2025 (see 90 FR 32650 through 32655), we believe that allowing eligible ACOs inexperienced with performance-based risk Medicare ACO initiatives to participate for a 5-year agreement period under the BASIC track's glide path, in which they could elect to remain under a one-sided model for 5 years, remains an important option to attract participation by ACOs that may need to gain experience with the accountable care model and invest in infrastructure and redesigned care processes for high quality and efficient healthcare service delivery before transitioning to performance-based risk. In particular, we continue to believe that this participation option serves as an important pathway for program entry and participation by eligible new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives, particularly in combination with the option to receive advance investment payments, and by eligible ACOs serving medically complex, high-cost populations, in combination with the program's current benchmarking methodology. We also believe that this participation option would remain important for attracting small, rural, safety-net providers to join or form ACOs.

However, as a departure from our position as described in CY 2023 PFS rulemaking, we are concerned that the current participation option permitting eligible ACOs to extend participation under the BASIC track's glide path to a second agreement period, in which they can participate under a one-sided model for the first two performance years (thereby allowing eligible ACOs to remain under a one-sided

model for up to 7 performance years) prior to progressing to two-sided risk, may weaken the incentives for ACOs to transition to two-sided risk, and for ACOs to make more meaningful changes to healthcare delivery during their first 5-year agreement period, or at the start of their second agreement period. Based on our experience with participation by ACOs that entered a first agreement period beginning on July 1, 2019 or January 1, 2020, and renewed to continue their participation in the Shared Savings Program for a second or subsequent agreement (see 90 FR 32654), ACOs tend to accept performance-based risk by their sixth performance year in the program, suggesting that one 5-year agreement period under a one-sided model would be sufficient for eligible ACOs to gain experience with the Shared Savings Program prior to accepting performance-based risk. Permitting ACOs to participate for longer periods under a one-sided model could impede CMS' achievement of the Shared Savings Program's goals. Alternatively, disallowing a second agreement period under the BASIC track's glide path, thereby requiring an ACO to enter Level E or the ENHANCED track by their second agreement period, would create greater incentives for ACOs to make the most meaningful changes in healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population.

Therefore, we proposed to use our authority under section 1899(i)(3) of the Act to limit the amount of time an ACO may participate in the Shared Savings Program under a one-sided model and require ACOs to more rapidly progress to higher levels of risk and potential reward under a two-sided model. We proposed that for agreement periods beginning on or after January 1, 2027, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives entering the BASIC track's glide path at Level A may continue to elect to remain under a one-sided model for all subsequent performance years of its first 5-year agreement period. However, we proposed such an ACO must enter its second or subsequent agreement period under Level E of the BASIC track or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track under the proposals at section III.F.4.b.(2).(b) of the CY 2026 PFS proposed rule). In so doing, this proposal limits the amount of time an ACO can participate under the BASIC track's glide path to one agreement period and also limits the amount of time under a one-sided model to, at most, 5 performance years.

As we explained in the CY 2026 PFS proposed rule (90 FR 32656), we believe this proposed approach strikes a balance between (1) policies that support growth of the Shared Savings Program by allowing for participation under a one-sided model for up to the entirety of an eligible ACO's first agreement period, and (2) policies encouraging participation in performance-based risk which we believe have the potential for increased effectiveness towards meeting the program's goals. This proposed approach retains an option for ACOs inexperienced with performance-based risk Medicare ACO initiatives, and that have no prior participation in the Shared Savings Program, to participate for their first agreement period under the BASIC track's glide path, with the option for ACOs to elect to remain under a one-sided model for this 5-year agreement period, or to advance along the glide path to higher levels of risk and potential reward. We recognized that commenters in earlier rulemaking have made various suggestions for the amount of time an ACO should be allowed to remain under a one-sided model, including 4 or 5 performance years or a full agreement period (as described in the CY 2026 PFS proposed rule at 90 FR 32651 citing 87 FR 69806 through 69807; 83 FR 67847). We explained that we prefer an approach that continues to allow eligible ACOs to participate for up to 5 performance years (the duration of such ACOs' first 5-year agreement period) under a one-sided model, which we believe is effective in attracting new ACOs to enter the Shared Savings Program, based on our analysis of participation trends. Additionally, using an approach that leverages the existing structure of the regulations for how we identify participation options for an ACO inexperienced with performance-based risk Medicare ACO initiatives entering a first agreement period reduces complexity in the program's policies, thereby facilitating ACOs' ability to ascertain the available participation options and allowing CMS to more readily implement the proposed approach to determining ACO eligibility for participation options. This proposed approach would also encourage ACOs inexperienced with performance-based risk Medicare ACO initiatives participating in the BASIC track's glide path for a first agreement period to prepare to take on two-sided risk no later than the start of their next 5-year agreement period in the Shared Savings Program, and thereby more quickly make meaningful changes to healthcare delivery, than the current approach.

To create the most meaningful incentive to change healthcare delivery and based on our experience with ACOs' selection of participation options, we believe it is appropriate to require ACOs to

transition to participation in Level E of the BASIC track or the ENHANCED track after no more than 1 agreement period under the BASIC track's glide path, which could include up to 5 performance years of participation under a one-sided model (for eligible ACOs). A number of factors informed our consideration of this approach. For one, under the benchmarking methodology applicable to agreement periods beginning on January 1, 2025, and in subsequent years, in accordance with § 425.652(a)(8)(ii), we adjust an ACO's historical benchmark based on the highest of three positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or HEBA. This approach to upwardly adjusting the benchmark could bolster the value of the rebased benchmark, calculated at § 425.652(c), for the ACO's second and subsequent agreement period. The potential upward adjustment to an ACO's benchmark through a regional adjustment, prior savings adjustment or HEBA, in combination with other policies under the existing financial methodology specified in subpart G, could help ensure there is sufficient incentive for ACOs to continue to participate in the program under higher levels of risk and potential reward.

Additionally, although we recognize participation in Level C and Level D may serve as a means for some ACOs to gain experience with performance-based risk, we believe the relatively low interest in participation in these financial models suggests it would be sufficient to only allow for participation in these lower levels of risk within the ACO's first agreement period under the BASIC track's glide path. As discussed in the CY 2026 PFS proposed rule (see 90 FR 32652 and 32653), in recent performance years (PY 2023 through 2025) there has been limited and declining participation in Level C and Level D of the BASIC track's glide path. Further, as we have observed based on more recent participation trends, once ACOs progress to performance-based risk, most ACOs do so by participating under Level E of the BASIC track, or the ENHANCED track. We believe that limiting additional participation in Levels C and D of the BASIC track to an ACO's first and only agreement period in the glide path (if eligible) will support our programmatic goals by facilitating ACOs' transition to two-sided models under which they have greater potential for risk and reward, and make more meaningful changes to healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population.

We proposed to specify related requirements in amendments to the Shared Savings Program regulations at § 425.600 and proposed technical and conforming changes elsewhere within § 425.600 and

at § 425.605. We proposed to amend § 425.600(g) introductory text, to limit the applicability of the requirements in this paragraph for determining an ACO's eligibility for the Shared Savings Program participation options to agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

At § 425.600, we proposed to redesignate paragraph (h) as paragraph (i), and proposed to add a new paragraph (h) that specifies the requirements CMS would use to determine an ACO's eligibility for Shared Savings Program participation options for agreement periods beginning on or after January 1, 2027, as described in further detail in the discussion that follows. Additionally, as we described in section III.F.4.b.(2).(b) of the CY 2026 PFS proposed rule (90 FR 32666 and 32667) and in greater detail in the discussion that follows, § 425.600(h)(3) includes a limited proposed exception for participation in the ENHANCED track by ACOs with less than 5,000 assigned beneficiaries in certain benchmark years. This limited proposed exception reflects our proposal that for agreement periods beginning on or after January 1, 2027, an ACO with fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both may only enter the BASIC track.

We proposed to specify in new § 425.600(h)(1) how CMS determines an ACO's eligibility for participation options, for agreement periods beginning on or after January 1, 2027, if an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20). We proposed to specify at § 425.600(h)(1) introductory text that if an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E, or the ENHANCED track, subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track specified in new § 425.600(h)(3) (described in section III.F.4.b.(2).(b) of the CY 2026 PFS proposed rule).

We proposed to specify under new § 425.600(h)(1)(i) that, for agreement periods beginning on or after January 1, 2027, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of one agreement period, and for which the progression along the glide path is specified at § 425.600(a)(4)(i)(C). We proposed to specify under new § 425.600(h)(1)(ii) that an ACO that enters an agreement period under the BASIC

track's glide path at any of the levels of risk and potential reward, Levels A through E, would be deemed to have completed one agreement period under the BASIC track's glide path. For the purpose of determining the ACO's prior participation in the BASIC track's glide path, we would consider whether the ACO satisfies either of the following: (A) the ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path; or (B) for a new ACO identified as a re-entering ACO (as defined at § 425.20), the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path.

We proposed to specify under new § 425.600(h)(1)(iii) that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but which is not eligible to enter the BASIC track's glide path, in accordance with the provisions of § 425.600(h)(1), may enter BASIC track Level E for all performance years of the agreement period, or the ENHANCED track, subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track specified in new § 425.600(h)(3) (described in section III.F.4.b.(2).(b) of the CY 2026 PFS proposed rule).

We proposed to adopt an approach similar to our existing requirements for determining the participation options of an ACO that is experienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20). We proposed to specify in new § 425.600(h)(2), for agreement periods beginning on or after January 1, 2027, if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E for all performance years of the agreement period, or the ENHANCED track, subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track specified in new § 425.600(h)(3) (described in section III.F.4.b.(2).(b) of the CY 2026 PFS proposed rule).

Additionally, we proposed at § 425.600(h)(3) to require, for agreement periods beginning on or after January 1, 2027, that if an ACO is determined to have fewer than 5,000 assigned beneficiaries in either the first benchmark year, second benchmark year, or both, in accordance with § 425.110(a)(3), the ACO may only enter the BASIC track. Under this approach, an ACO prohibited from participating in the

ENHANCED track because it has fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, may enter an agreement period beginning on or after January 1, 2027, in the BASIC track, at a level of risk and potential reward otherwise determined in accordance with the proposed requirements of new § 425.600(h), as follows:

- An ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives may enter the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E (if eligible in accordance with the proposed requirements at new § 425.600(h)(1)), or BASIC track Level E for all performance years of the agreement period.
- An ACO determined to be experienced with performance-based risk Medicare ACO initiatives may enter BASIC track Level E for all performance years of the agreement period.

We proposed to apply this modified approach in determining ACOs' participation options for agreement periods beginning on or after January 1, 2027, since the application cycle for the January 1, 2027 start date (anticipated to occur in CY 2026) would be the next cycle following the anticipated effective date for the CY 2026 PFS final rule of January 1, 2026. We explained in the CY 2026 PFS proposed rule that the majority of the application cycle for the January 1, 2026 start date, spanning Spring – Fall 2025, would occur before this rule could be finalized.

As we described in the CY 2026 PFS proposed rule (90 FR 32657), the criteria CMS used to determine an ACO's eligibility to enter an agreement period, at § 425.600(g), that were applied in determining participation options for ACOs entering an agreement period beginning on January 1, 2024 or January 1, 2025, would also be applied in determining participation options for ACOs entering an agreement period beginning on January 1, 2026. We explained that, if finalized, the proposed criteria to determine an ACO's eligibility to enter an agreement period, specified under new § 425.600(h), would be applied in determining participation options for ACOs entering an agreement period beginning on or after January 1, 2027. That is, we would apply the modified approach (if finalized) consistently across new ACO applicants, renewing ACOs (as defined at § 425.20) and re-entering ACOs (as defined at § 425.20) in determining ACO participation options for agreement periods beginning on or after January 1, 2027.

We recognized that with the changes in the program's policies over time, there are currently ACOs participating in agreement periods, to which different requirements apply for determining the

ACO's participation options, in accordance with § 425.600. As we explained in the CY 2026 PFS proposed rule (90 FR 32657 and 32658), this approach would change how we determine an ACO's eligibility for Shared Savings Program participation options, program wide. If we finalized the proposed approach, ACOs currently participating in a first agreement period under the BASIC track's glide path (with 2022, 2023, 2024, and 2025 start dates) and ACOs entering a first agreement period in the BASIC track's glide path with the January 1, 2026 start date, would be ineligible to enter a subsequent agreement period under the BASIC track's glide path, with a start date on or after January 1, 2027. Instead, such ACOs, should they continue their participation in the Shared Savings Program for a second or subsequent agreement period, could only select to participate in Level E of the BASIC track or the ENHANCED track (subject to the exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track). Based on the number of ACOs currently participating in a first agreement period under a one-sided model of the BASIC track's glide path, we anticipate the approach could impact 57 ACOs currently participating in Level A of the BASIC track (7 ACOs that are 2022 starters, 7 ACOs that are 2023 starters, 26 ACOs that are 2024 starters, and 17 ACOs that are 2025 starters) where these ACOs could participate in a one-sided model for a maximum of 5 performance years (instead of 7 performance years).[395] We explained that, at the time of the CY 2026 PFS proposed rule, the number of eligible 2026 starters that may enter the BASIC track's glide path at Level A is yet to be determined.

In the CY 2026 PFS proposed rule (90 FR 32658), we acknowledged that ACOs currently participating in Level A of the BASIC track may have joined or remained in the Shared Savings Program relying on the availability of participation options established with the CY 2023 PFS final rule. We further acknowledge that the proposed modifications to limit participation in the BASIC track's glide path and the amount of time an ACO may remain under a one-sided model, if finalized, may alter the ACOs' incentives to remain in the Shared Savings Program. As discussed in the Regulatory Impact Analysis of the CY 2026 PFS proposed rule (90 FR 32816), we project that discontinuing the option for ACOs to

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[395] Total count of ACOs participating in Level A of the BASIC track, among ACOs entering a first agreement period in the Shared Savings Program by start date, as of performance year 2025. See *Data.CMS.gov*, Medicare Shared Savings Program, Accountable Care Organizations, Public Use File (by performance year, for PY 2025), available at https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations.

participate under a second agreement period in the BASIC track's glide path may create potential uncertainty for some ACOs on continuing in the program. We further explain that, notwithstanding this uncertainty for some ACOs, the proposed changes have the potential to improve care management and increase savings from other ACOs that successfully manage the transition to performance-based risk earlier than they would have. We explained that we did not find the concern about the potential attrition by ACOs unwilling to transition to performance-based risk a compelling reason to forgo the proposed changes to the Shared Savings Program's participation options. We explained our belief that the program's benchmarking methodology includes sufficient incentive for ACOs to continue to participate in the program. Additionally, based on trends in program participation, we anticipate that at least some of the ACOs currently participating under Level A of the BASIC track may elect to transition to a two-sided model level of the BASIC track during the remaining performance years of their current agreement period or would transition to a two-sided risk model at the beginning of their next agreement period notwithstanding the proposed change. We stated, more generally, our belief that the concern about potential for loss of participation by ACOs unwilling to progress to two-sided risk with their second agreement period is balanced against, and outweighed by, the potential for increased effectiveness from other ACOs that continue to participate and successfully manage an earlier transition to performance-based risk, and establishing a policy that we believe will further advance the program's goals.

In the CY 2026 PFS proposed rule (90 FR 32658), we provided several examples, to illustrate how the proposed policies for determining ACO participation options would apply. Take for example a new ACO inexperienced with performance-based risk Medicare ACO initiatives that enters the BASIC track's glide path at Level A for an agreement period beginning on January 1, 2027, and concluding December 31, 2031, based on the criteria used to determine ACO participation options specified under new § 425.600(h) (as proposed). Under this example, the ACO would be able to elect to remain under Level A for all subsequent performance years of its agreement period (performance years 2028 through 2031) in accordance with §425.600(a)(4)(i)(C)(*3*). Assume for this example the ACO chooses to remain under Level A for the duration of its first agreement period and applies to renew to continue its participation in the Shared Savings Program for a new agreement period beginning on January 1, 2032. Under the proposed approach, the ACO would be considered inexperienced with performance-based risk

Medicare ACO initiatives and would be identified by CMS as having previously entered an agreement period under the BASIC track's glide path and deemed to have completed one agreement period under the BASIC track's glide path. As a result, the ACO would be ineligible to enter the BASIC track's glide path and would be limited to participating under Level E of the BASIC track, or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track) for its second agreement period beginning on January 1, 2032, or a subsequent agreement period.

As another example, consider a new ACO inexperienced with performance-based risk Medicare ACO initiatives that enters the BASIC track's glide path at Level A for an agreement period beginning on January 1, 2026, based on the criteria used to determine ACO participation options specified at § 425.600(g). Under this example, the ACO elects to remain under Level A for all subsequent performance years of its agreement period in accordance with § 425.600(a)(4)(i)(C)(*3*). If the ACO applies to renew to continue its participation in the Shared Savings Program for a new agreement period, beginning on January 1, 2031, under the proposed approach, the ACO would be considered inexperienced with performance-based risk Medicare ACO initiatives, and would be identified by CMS as having previously entered an agreement period under the BASIC track's glide path and deemed to have completed one agreement period under the BASIC track's glide path. As a result, the ACO would be ineligible to enter the BASIC track's glide path and would be limited to participating under Level E of the BASIC track, or the ENHANCED track (subject to the proposed exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track) for its second agreement period beginning on January 1, 2031, or a subsequent agreement period. Similarly situated ACOs that entered an agreement period beginning on January 1, 2022, January 1, 2023, January 1, 2024, or January 1, 2025 that elected to remain under a one-sided model of the BASIC track's glide path for the duration of their 5-year agreement period, and are applying to renew to continue their participation in the program for a new agreement period, would have the same participation options as the ACO in this example.

As described in the CY 2026 PFS proposed rule (90 FR 32658 and 32659), we proposed to use our authority under section 1899(i)(3) of the Act to change the requirements for ACOs' progression to

performance-based risk under the program's participation options. To adopt requirements in connection with participation under a two-sided model of the Shared Savings Program under section 1899(i)(3) of the Act, we must determine that doing so will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. As we have discussed in earlier rulemaking, in connection with the use of this authority for establishing the program's participation options (see 76 FR 67904 through 67909, 80 FR 32771 and 32772, 83 FR 67834 through 67841), the program's two-sided models provide an additional opportunity for ACOs to enter a risk-sharing arrangement and accept greater responsibility for beneficiary care. Under the proposed approach we would modify the Shared Savings Program participation options to reduce the maximum amount of time an ACO may participate under the BASIC track's glide path from two agreement periods to one agreement period, thereby limiting the amount of time an ACO may remain under a one-sided model to at most 5 performance years. We would also require ACOs inexperienced with performance-based risk Medicare ACO initiatives to progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track, compared to the current requirements. Under the proposed approach, ACOs entering and continuing their participation in the Shared Savings Program would continue working towards meeting the program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries. In the CY 2026 PFS proposed rule, we described our belief that requiring ACOs to more quickly progress to performance-based risk would create incentives for ACOs to make more meaningful changes to healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population. As discussed in the Regulatory Impact Analysis of the CY 2026 PFS proposed rule (see 90 FR 32817 and 32818), we project that the proposed changes in participation options, in combination with other proposed changes to the statutory payment model in the CY 2026 PFS proposed rule, as well as current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program, and would not be expected to increase program expenditures relative to those of the statutory payment model.

We stated that we will continue to reexamine this projection to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement

under section 1899(i)(3)(B) of the Act. If we later determined that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

Additionally, we proposed to make the following technical and conforming changes, for completeness and clarity, to reflect our proposals to redesignate existing § 425.600(h) as paragraph (i), and to specify in a newly added paragraph (h) of § 425.600 the requirements for determining an ACO's eligibility for Shared Savings Program participation options for agreement periods beginning on or after January 1, 2027.

- Amending a cross-reference within § 425.600(a)(4)(i)(C)(*1*) to include a reference to proposed new paragraph (h)(1) at § 425.600.
- Amending cross-references within § 425.600(a)(4)(ii) and § 425.605(d)(1) introductory text to include a reference to proposed new paragraph (h) at § 425.600.
- Amending cross-references within § 425.600(a)(4)(i)(C)(*2*)(*iii*) and § 425.605(b)(2)(ii)(E) to refer to provisions within proposed newly redesignated paragraph (i) at § 425.600 instead of existing paragraph (h).
- Revising § 425.605(d)(2), describing the level of risk and reward specified for Level E of the BASIC track. Currently this paragraph specifies Level E risk and reward at § 425.605(d)(1)(v) applies to an ACO eligible to enter the BASIC track that is determined to be experienced with performance-based risk Medicare ACO initiatives as specified at § 425.600(d) or § 425.600(g). We proposed to amend this provision for greater consistency with the proposed approach to determining participation options and new § 425.600(h)(1)(iii) and (h)(2), under which for agreement periods beginning on or after January 1, 2027, an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives that is not eligible to enter the BASIC track's glide path, or an ACO that is determined to be experienced with performance-based risk Medicare ACO initiatives may enter either the BASIC track Level E for all performance years of the agreement period (among other participation options). Therefore, in the CY 2026 PFS proposed rule, we proposed to revise § 425.605(d)(2) to state more generally the following (restated in this final rule with minor corrections for clarity): if the ACO enters the BASIC track at Level

E as specified under § 425.600(d), (g), or (h), the level of risk and reward specified in § 425.605(d)(1)(v) applies to all performance years of an ACO's agreement period.

We solicited comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to decrease the amount of time an ACO can participate under a one-sided model under the BASIC track's glide path from 7 to 5 years. Several commenters supported CMS' goal of moving ACOs towards higher levels of accountability. Many commenters agreed that upside-only performance tracks are necessary but advancement into two-sided risk tracks is essential for incentivizing care improvements and reducing healthcare spending. A commenter supported the proposal for faster transitions to two-sided risk, noting that Shared Savings Program results continue to underscore that significant savings come from two-sided risk arrangements. Some commenters who supported the proposed changes also recommended that the number of performance years within a one-sided model is not lowered any further than 5 years.

Response: We appreciate commenters' support for the proposed policy and their acknowledgement that ACO participation under two-sided risk models continues to generate savings for the Medicare program. For the reasons stated earlier in this section of this final rule, we continue to believe that the proposed approach strikes a balance between (1) policies that support growth of the Shared Savings Program by allowing for participation under a one-sided model for up to the entirety of an eligible ACO's first agreement period, and (2) policies encouraging participation in performance-based risk which we believe have the potential for increased effectiveness towards meeting the program's goals. In response to commenters urging that CMS not further reduce the number of performance years an ACO may remain under a one-sided model to be less than 5 years, we note that we continue to believe that maintaining a participation option for eligible ACOs inexperienced with performance-based risk Medicare ACO initiatives to enter and remain under a one-sided model for 5 years, is an important means for attracting participation by ACOs that may need to gain experience with the accountable care model. As reflected in the commenters' remarks, we also agree that ACO advancement into performance-based risk is essential for incentivizing care improvements for beneficiaries and reducing Medicare spending.

Comment: Many commenters who supported the proposed changes also encouraged CMS to

maintain the existing policy for ACOs currently participating in their first agreement period under BASIC track Level A and ACOs entering their first agreement period with a January 1, 2026 start date. Some of these commenters also recommended delaying the proposed policy by two years for ACOs that joined the Shared Savings Program in performance year (PY) 2022 and to allow these ACOs to transition to higher-risk arrangements according to the participation options that were in effect when they signed their original participation agreement.

Another commenter supported the proposal but recommended that CMS allow ACOs to maintain participation in the BASIC track's Level C and Level D during their second agreement period prior to being required to participate in BASIC track Level E or the ENHANCED track. Some commenters noted that requiring renewing ACOs to move into downside risk before they are ready could destabilize the Shared Savings Program, and an exception to the proposed policy (requiring participation in Level E of subsequent BASIC track agreements) would ensure that the ACOs assume risk after 7 years as originally anticipated, albeit a lower level of risk. Another commenter suggested CMS "maintain the existing policy for ACOs entering their first agreement period with a January 1, 2026 start date (that is, those ACOs should remain eligible for an additional two years under a one-sided model upon entering their second agreement period)." A few commenters expressed a similar sentiment, suggesting that CMS apply the proposed policy only to new ACOs as currently participating ACOs entered the Shared Savings Program under the existing glide path and have been using shared savings to build infrastructure and capabilities necessary for risk-bearing arrangements. Similarly, another commenter stated that CMS should not require participants to advance into downside financial risk too quickly as there is no ability to move back to one-sided risk in future years due to extenuating circumstances. More generally, a commenter noted that ACOs transitioning from one-sided to two-sided risk levels, or remaining under two-sided risk in the BASIC track, generate higher levels of average net savings compared to those that remain in one-sided risk, because there is an inherent difference between these ACOs as ACOs that progress to two-sided risk are confident in their ability to succeed and earn shared savings.

Response: We continue to believe that decreasing the maximum amount of time an ACO can participate in one-sided risk under the BASIC track from 7 to 5 years will promote direct accountability for health outcomes and the costs of beneficiary care, while improving the quality of care for Medicare

beneficiaries. We disagree with commenters' suggestions to allow all ACOs or select ACOs (for example, based on their initial agreement start date) to remain under the one-sided model for 7 years. We believe such a policy design would, at best, maintain the status quo of the program, and therefore continue a pattern where ACOs are allowed to remain under the one-sided model for a significant number of years without added incentives to become accountable for the cost and quality of care for their assigned populations. As described in the CY 2026 PFS proposed rule (90 FR 32652 and 32653) and restated elsewhere in this section of this final rule, in recent performance years we have observed that fewer ACOs are entering and participating under a one-sided model compared to two-sided models. Specifically, participation in one-sided models is lower in PY 2025 (29 percent of ACOs) compared to PY 2022 (41 percent of ACOs), and PY 2023 and PY 2024 (33 percent of ACOs for each PY).

Further, from program participation for PYs 2022 through 2025, we have observed that when ACOs participate under two-sided risk, they opt for higher levels of risk and reward; relatively few ACOs participate under Level C or Level D of the BASIC track's glide path, compared to participation in Level E of the BASIC track or the ENHANCED track. Additionally, among ACOs participating under two-sided risk, more ACOs are participating under the highest level of risk and potential reward offered by the ENHANCED track than in Levels C, D and E of the BASIC track combined. It does not appear that ACOs necessarily need to progress along the glide path in their second agreement period as the participation trends suggest ACOs are ready to assume higher levels of risk and reward once they begin participating under a risk arrangement. As explained in the CY 2026 PFS proposed rule (90 FR 23656), we believe that limiting additional participation in Levels C and D of the BASIC track to an ACO's first and only agreement period in the glide path (if eligible) will support our programmatic goals by facilitating ACOs' transition to two-sided models under which they have greater potential for risk and reward, and make more meaningful changes to healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population.

We understand the commenters’ view that ACOs may have planned investments into their infrastructure and operational processes based upon the participation options codified at the time they began participating in the program. However, the data we have detailed in the CY 2026 PFS proposed rule, and reiterated in this final rule, does not suggest ACOs require 7 years to successfully transition to

performance-based risk. We believe the historical success demonstrated by ACOs participating under a two-sided model is significant enough to apply the proposed policy to all eligible ACOs and not provide exceptions for any subset of ACOs.

Comment: Some commenters agreed with the move to more quickly transition ACOs to downside risk to ensure ACOs have greater incentives to generate savings for the Medicare program. However, several of these commenters expressed concerns regarding program attrition, stating an accelerated timeline for making the transition to two-sided risk will drive ACOs to exit the Shared Savings Program, potentially outweighing the efficiencies that could be gained. One commenter stated increased risk should be balanced against sufficient participation incentives and strong program design given that the Shared Savings Program is a voluntary program and recommended that CMS monitor participation trends for program attrition. The commenter did not provide specific examples or suggestions for participation incentives and strong program design. Another commenter recommended CMS focus additional ACO support resources on those ACOs transitioning from their first to second agreement period.

Response: We thank commenters for their support and agree that increased risk should be balanced against sufficient participation incentives and strong program design. As demonstrated throughout this final rule, CMS monitors the participation trends of ACOs, including attrition rates, when developing and implementing regulatory changes particularly policies impacting participation options. Particularly in light of program goals to grow provider participation in the Shared Savings Program and to increase participation in two-sided risk models, we will continue to monitor such trends and identify ways to encourage participation, incentivize care improvements for beneficiaries and reduce Medicare spending.

Additionally, with more recent rulemaking we have modified the Shared Savings Program to include participation and payment options intended to support ACOs progressing to performance-based risk. For example, healthcare providers have reported they require upfront capital to make the necessary investments to succeed in accountable care; therefore with the CY 2023 PFS final rule (87 FR 69782 through 69805), we finalized the availability of Advance Investment Payments (AIP) for eligible ACOs entering agreement periods beginning on or after January 1, 2024 (as specified under § 425.630). Under this payment option, eligible low revenue ACOs inexperienced with performance-based risk Medicare

ACO initiatives and that are new to the Shared Savings Program (that is, not a renewing or re-entering ACO) may receive a one-time fixed payment and per beneficiary quarterly payments for the first 2 performance years of their 5-year agreement period. With the CY 2025 PFS final rule (89 FR 98132 through 98153), we established the option for eligible renewing ACOs to receive prepaid shared savings, starting with the performance year beginning on January 1, 2026 (as specified under § 425.640), to provide an additional cash flow option to ACOs with an established history of earning shared savings that will encourage their investment in activities that reduce costs for the Medicare program and improve the quality of care provided to their assigned beneficiaries. This in turn may enable ACOs to increase their shared savings as they make investments in direct beneficiary services to improve care coordination and quality through staffing or health care infrastructure.

CMS also provides participating ACOs with annual and quarterly expenditure and utilization reports (see § 425.702) and beneficiary identifiable claims data (see § 425.704) for supporting beneficiary care coordination. The more recent payment options, and the program's data sharing policies, are just a few examples of program operations we have implemented in support of ACOs in achieving the Shared Savings Program's goals.

As we gain experience with the modified participation options we are finalizing with this final rule, and our other program policies, we will continue to explore opportunities to support participation by ACOs, including with the transition to performance-based risk. Should we decide that additional modifications to the program's policies are needed, we would propose such changes through future notice and comment rulemaking.

Comment: Several commenters opposed the proposed policy, with the majority of those commenters expressing the need for additional participation options for certain types of providers and ACOs, including rural and safety net providers, community health center-led ACOs, physician-led ACOs, and federally qualified health centers (FQHCs), to continue participating under a one-sided model for a longer period of time. These commenters suggested CMS continue to monitor and refine the program's participation options to ensure that participation by these types of ACOs is not disproportionately impacted by the proposal. Some commenters stated that the proposed changes create a financial and operational risk that many ACOs cannot realistically adopt in such a short period of time, as smaller,

more rural, and specialty-specific ACOs often lack the resources and infrastructure available to large, well-integrated healthcare systems. Similarly, a commenter stated that a 5-year one-sided risk glidepath is too short and overly aggressive for FQHCs. Some commenters suggested that CMS "consider rural-specific flexibilities and support mechanisms to safeguard access", suggesting ACOs with large rural beneficiary populations should be measured by improvements in access to care, not just financial outcomes. Some commenters suggested modifying existing APMs to provide "a set of waivers specific to safety-net providers in APMs", develop new ACO tracks/total cost of care models focused solely on rural and underserved populations, or global budgets, prospective payments, or lower the minimum savings rate for ACOs participating in a two-sided model. Some commenters noted that providing an exception to allow certain ACOs to remain under one-sided risk for longer could entice more community health centers to participate in the Shared Savings Program and look further into adopting VBC models. These commenters expressed that ACOs with community health centers (CHCs) "served more beneficiaries with lower incomes, those with disabilities, or those with racial differences, while simultaneously increasing several quality measure outcomes related to the delivery of preventive care, compared to ACOs without CHC participation."

Response: Since the inception of the Shared Savings Program, we have encouraged participation by ACOs composed of various providers/suppliers, including Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and FQHCs,[396] and have over time considered the timing of transition to risk by small, rural ACOs and ACOs comprised of safety net providers, among others. Historically, we have observed that ACOs in performance-based risk tracks have better financial performance than ACOs in shared savings only tracks, and that low revenue ACOs (which tend to be small, physician-only and rural ACOs) have better financial performance than high revenue ACOs (whose compositions often include institutional providers, particularly hospitals and health systems) (see 83 FR 67820 and 67921). As described elsewhere in this section of this final rule, we believe we have enough evidence to show that 5 years under a one-sided model is enough time for ACOs to successfully transition to performance-based risk. We proposed to apply this modified approach in determining ACOs' participation options for new agreement periods beginning on or after January 1, 2027, and we believe this proposed timing of

[396] Section 425.102 describes providers and suppliers eligible to form or participate in a Shared Savings Program ACO.

applicability provides currently participating ACOs sufficient time to strategize the operational changes necessary to support their transition to performance-based risk.

We believe the Shared Savings Program offers sufficient incentives that encourage and support safety-net providers to participate in ACOs as evidenced by our participation trends. We have seen an increase in program participation from safety net providers, particularly in ACOs participating under agreement periods beginning on or after July 1, 2019, following the changes to the Shared Savings Program finalized with the December 2018 final rule. For example, during the PY beginning on July 1, 2019, 2,358 FQHCs, 1,324 RHCs, and 435 CAHs participated in the Shared Savings Program.[397] In PY 2025, we have 7,036 FQHCs, 2,872 RHCs, and 547 CAHs participating in the Shared Savings Program.[398] As evidenced by this participation data, we continue to see participation among safety net providers increase as CMS has finalized changes to policies around the progression to performance-based risk in the Shared Savings Program, including requirements for ACOs to transition more rapidly to higher levels of risk and potential reward.

While reviewing these comments we further investigated participation data for ACOs which have at least one FQHC, RHC, or CAH participating in their ACO. Among ACOs that entered a one-sided model of the BASIC track's glide path, for a first agreement period beginning on July 1, 2019 or January 1, 2020 (a subset of ACOs described in the CY 2026 PFS proposed rule at 90 FR 32654 and 32655), we identified 15 ACOs that included one or more FQHC, RHC, or CAH and have remained in the Shared Savings Program until PY 2025. Of these 15 ACOs, 10 ACOs progressed into a two-sided model prior to PY 2025 or within their initial 5-year agreement period. Additionally, we found that ACOs comprised of CAHs, RHCs and FQHCs have performed well under a two-sided model. We did an internal analysis of all two-sided ACOs included in PY 2024 financial reconciliation. We identified 185 ACOs which included at least one FQHC, RHC, or CAH among their ACO providers/suppliers. Of the 185 ACOs, 155 ACOs (84 percent) earned shared savings. Additionally, of these 155 ACOs the average number of CAHs, RHCs and FQHCs participating in the ACOs was 38. We also looked into the 9 two-sided ACOs with at

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[397] See "Shared Savings Program Fast Facts – As of July 1, 2019", within "Fast Facts Archives", available at https://www.cms.gov/media/638196.
[398] See "Shared Savings Program Fast Facts – As of January 1, 2025", available at https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf.

least one FQHC, RHC, or CAH among their ACO providers/suppliers who had shared losses, and among these 9 ACOs, the average number of CAHs, RHCs and FQHCs was 11. This data suggests ACOs that have CAHs, RHCs and FQHCs participants are able to successfully participate in the Shared Savings Program and earn shared savings under a two-sided model. We do not believe it is necessary to provide special exceptions to our proposed policy for ACOs that include FQHCs, RHCs, or CAHs among their ACO providers/suppliers. We will continue to monitor participation trends and explore ways to encourage participation of CAHs, RHCs and FQHCs in the Shared Savings Program and consider policies for future rulemaking as appropriate.

We also note that we created the AIP payment option and believe it can be a very helpful resource for the community health center-led ACOs. AIPs are designed to provide upfront funding to assist new, low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives establish their ACOs and succeed in the Shared Savings Program. We believe this type of upfront funding aids ACOs in their development such that they could take on downside risk more quickly.

Comment: A commenter did not agree with CMS' analysis regarding ACOs inexperienced with performance-based risk, stating that the data does not conclude that, absent the 7-year horizon to transition to full risk-sharing, a high percentage of ACOs would still enter the program. Another commenter opposed to the proposed changes noted that many ACOs are moving to risk before the current regulation requires them to and many ACOs are progressing directly to BASIC track Level E or the ENHANCED track and bypassing BASIC track Levels C and D, therefore they expressed these regulatory changes are unnecessary because many ACOs are already exhibiting the behavior we proposed to require. Another commenter suggested that ACOs participating under a one-sided model are more efficient than ACOs participating under a two-sided model and that ACOs can achieve Medicare beneficiary expenditure reduction through efficiency improvements such as improved care management and coordination without switching to a two-sided model.

Response: We acknowledge that it is difficult to know how many, if any, ACOs joined the Shared Savings Program specifically because they intended to participate for a full 7 years under a one-sided model. As described in the CY 2026 PFS proposed rule (90 FR 32658), elsewhere in this section of this final rule, and in the Regulatory Impact Analysis of this final rule, we project that discontinuing the

option for ACOs to participate under a second agreement period in the BASIC track's glide path may create potential uncertainty for some ACOs on continuing in the program. We continue to believe that the loss of participation by ACOs unwilling to progress to two-sided risk with their second agreement period is balanced against, and outweighed by, the potential for increased effectiveness from other ACOs that continue to participate and successfully manage an earlier transition to performance-based risk, and establishing a policy that we believe will further advance the program's goals.

We disagree with the commenter suggesting the proposed policy is unnecessary because many ACOs have already moved to a two-sided model. We also acknowledge ACOs under one-sided models also achieve expenditure reductions through efficiency improvements. However, our analysis shows that ACOs under two-sided models have demonstrated greater effectiveness in implementing efficiencies. We believe this approach is appropriate to support our programmatic goals by facilitating more ACOs' transitions to two-sided models under which they have greater potential for risk and reward, and make more meaningful changes to healthcare delivery, and in turn cost and quality improvements, for their assigned Medicare FFS beneficiary population.

Our data suggests that ACOs transitioning to or remaining in two-sided model levels of the BASIC track outperform ACOs remaining in one-sided models of the BASIC track. As described previously in this section, we analyzed the financial performance of groups of ACOs that participated in both PYs 2022 and 2023. Cohorts were assembled based on ACO track/level of participation in PY 2022 and PY 2023. This analysis shows the highest rates of average net savings among the following groups: (1) ACOs remaining in two-sided models of the BASIC track (Levels C, D or E) over the 2-year period; and (2) ACOs moving from a one-sided model of the BASIC track (Level A or B) to a two-sided model of the BASIC track (Levels C, D or E) over PY 2022 to PY 2023. These cohorts also demonstrated the lowest average unadjusted per capita spending growth rates over this 2-year period. These findings suggest that ACOs transitioning to or remaining in two-sided model levels of the BASIC track outperform ACOs remaining in one-sided models of the BASIC track, and we refer commenters to discussion in the Regulatory Impact Analysis of this final rule for a more detailed explanation of the analysis underlying these findings.

After consideration of public comments, we are finalizing our proposal. For agreement periods

beginning on or after January 1, 2027, an ACO identified as inexperienced with performance-based risk Medicare ACO initiatives (defined in § 425.20) may participate in the Shared Savings Program under a one-sided model for up to 5 performance years under the ACO's first agreement period in the BASIC track's glide path (if eligible). This modifies the current policy allowing a maximum of 7 performance years spanning two agreement periods in the BASIC track's glide path. We will also require ACOs inexperienced with performance-based risk Medicare ACO initiatives to progress more rapidly to higher levels of risk and potential reward under a two-sided model by their second agreement period, by requiring them to participate under Level E of the BASIC track or the ENHANCED track. BASIC track Level E and the ENHANCED track each qualify as an Advanced Alternative Payment Model (APM) under the Quality Payment Program.

Specifically, we will amend § 425.600 to redesignate paragraph (h) as paragraph (i) and add a new paragraph (h) that specifies the requirements CMS would use to determine an ACO's eligibility for Shared Savings Program participation options for agreement periods beginning on or after January 1, 2027. Additionally, § 425.600(h)(3) will include a limited exception for participation in the ENHANCED track by ACOs with less than 5,000 assigned beneficiaries in certain benchmark years. This limited exception reflects the requirement that for agreement periods beginning on or after January 1, 2027, an ACO with fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both may only enter the BASIC track.

We will specify in new § 425.600(h)(1) how CMS determines an ACO's eligibility for participation options for agreement periods beginning on or after January 1, 2027, if an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives (as defined at § 425.20). Section 425.600(h)(1) will provide that if an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E, or the ENHANCED track, subject to the exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track, specified in new § 425.600(h)(3) (described in section III.F.4.b.(2).(b) of this final rule).

We will specify under new § 425.600(h)(1)(i) that, for agreement periods beginning on or after

January 1, 2027, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of one agreement period, and for which the progression along the glide path is specified at § 425.600(a)(4)(i)(C). We will specify under new § 425.600(h)(1)(ii) that an ACO that enters an agreement period under the BASIC track's glide path at any of the levels of risk and potential reward, Levels A through E, would be deemed to have completed one agreement period under the BASIC track's glide path. For the purpose of determining the ACO's prior participation in the BASIC track's glide path, we will consider whether the ACO satisfies either of the following criteria: (A) the ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path; or (B) for a new ACO identified as a re-entering ACO (as defined at § 425.20), the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path.

Finally, we will specify under new § 425.600(h)(1)(iii) that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but which is not eligible to enter the BASIC track's glide path, in accordance with § 425.600(h)(1), may enter BASIC track Level E for all performance years of the agreement period, or the ENHANCED track, subject to the exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track, specified in new § 425.600(h)(3).

3. Eligibility Requirements

a. ACO Participant Change of Ownership (CHOW) Scenarios

(1) Background

In the June 2015 final rule (80 FR 32707 through 32712), we added § 425.118(a) and (b) to establish requirements for maintaining, updating, and submitting to CMS an accurate and complete ACO participant list.

Section 425.118(a) includes requirements for ACOs to submit and certify their ACO participant lists before the start of each agreement period and each performance year thereafter, as well as at other times. Section 425.118(b)(1) and (2) authorize ACOs to make additions or deletions to their ACO participant lists, and § 425.118(b)(3) authorizes CMS to make annual adjustments based upon ACO

participant list additions or deletions for purposes of the ACO's assignment, historical benchmark, financial calculations, and quality reporting. Additionally, CMS has the authority at § 425.305(a) to screen ACOs, ACO participants, and ACO providers/suppliers for program integrity purposes, as well to impose safeguards where negative program integrity history is present.

To be eligible to participate in the Shared Savings Program, as specified at § 425.118(a)(1), an ACO must maintain, update, and submit to CMS an accurate and complete ACO participant list. The ACO participant list identifies each ACO participant by its Medicare-enrolled TIN and legal business name (LBN). ACO participant agreements must require an ACO participant to report changes in enrollment information to the ACO within 30 days of the change (§ 425.116(a)(6)) and in accordance with Shared Savings Program requirements (§ 425.116(a)(3)).

CMS uses the certified ACO participant list to conduct critical oversight functions of the Shared Savings Program for downstream operations, such as establishing historical benchmarks; data sharing; financial performance; quality reporting; public reporting; and program eligibility. Changes to the certified ACO participant list can impact an ACO's overall eligibility to participate in the Shared Savings Program. For example, removing an ACO participant could drop the ACO's overall number of assigned Medicare fee-for-service beneficiaries below the 5,000 minimum required for participation in the Shared Savings Program (§ 425.110(a)(1)). Additionally, modifications to the certified ACO participant list can affect whether an ACO is determined to be a "low revenue ACO" or "high revenue ACO," as well as CMS' determination regarding whether an ACO is "experienced with performance-based risk Medicare ACO initiatives" or "inexperienced with performance-based risk Medicare ACO initiatives," as defined in § 425.20. Because the ACO participant list has downstream effects on an ACO's participation in the Shared Savings Program, changes to the certified ACO participant list are only permitted during the annual Shared Savings Program change request cycle. Absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the performance year (§ 425.118(b)(3)(ii)). Limiting additions of new ACO participants

or revisions to an existing ACO participant on an ACO's participant list to one annual change request cycle ensures the integrity of program operations for both CMS and ACOs. CMS has sole discretion to determine whether unusual circumstances exist that warrant such adjustments (§ 425.118(b)(3)(ii)).

Before the start of an agreement period, before each performance year thereafter, and at such other times as specified by CMS, the ACO must submit to CMS an ACO participant list (§ 425.118(a)(2)). As operationalized, ACOs are able to add an entity to their previously certified ACO participant list according to the form and manner specified by CMS (§ 425.118(b)(1)). To add a new ACO participant TIN, an ACO must submit a change request by the final deadline established by CMS (§ 425.118(b)(1)). Currently, change requests are only accepted by CMS during the change request cycle. All additions to the ACO participant list approved by CMS during the change request cycle are effective on January 1 of the next performance year (§ 425.118(b)(1)(ii)).

A change of ownership (CHOW) can occur when an ACO participant is purchased (or leased) by another organization. In such a case, the CHOW often results in the transfer of the previous owner's Medicare Identification Number and provider agreement (including the previous owner's outstanding Medicare debts) to the new owner. (See generally, § 489.18(c)). If the purchaser or lessee elects not to accept a transfer of the provider agreement, then the old agreement should be terminated, and the purchaser or lessee is considered a new applicant and must initially enroll in Medicare.[399]

To notify CMS of the CHOW, an ACO participant submits the appropriate Medicare Enrollment Application form to their Medicare Administrative Contractor (MAC) or in the Provider Enrollment, Chain, and Ownership System (PECOS).[400] The MAC uses the forms and required supporting documentation to document and identify changes in ownership and/or subsequent changes in TINs and Medicare Identification Numbers. When an ACO participant undergoes a CHOW resulting in a change to the TIN used for the Shared Savings Program, the ACO must provide documentation of the CHOW in a new change request to add the surviving Medicare enrolled TIN with no prior Medicare billing claims

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[399] See generally Paper Enrollment Applications at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/enrollment-applications.

[400] Medicare providers and suppliers can enroll using the PECOS. PECOS is a web-based platform managed by CMS that facilitates the enrollment process for Medicare providers and suppliers. See CMS.gov website, Medicare Enrollment for Providers & Suppliers webpage, at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos. See also, PECOS, Medicare Enrollment for Providers and Suppliers, at https://pecos.cms.hhs.gov/pecos/help-main/faq.jsp (with Frequently Asked Questions including information on CHOW).

history to its ACO participant list. This allows CMS to appropriately track eligibility and other program requirements as well as perform other program operations such as beneficiary assignment, benchmark and performance year expenditure calculations, and determinations of shared savings and losses for ACOs with ACO participants that have undergone a CHOW.

In some circumstances, an ACO participant CHOW could result in one Medicare-enrolled TIN being absorbed into an existing Medicare-enrolled TIN. This would mean the surviving ACO participant TIN would have Medicare billing claims history or other factors affecting an ACO's overall performance or benchmarking. Under this scenario, the surviving TIN could have a patient population and providers and suppliers who were not accounted for when CMS established the ACO's benchmarks. Such a scenario could lead to variation in the patient population seen during the performance year compared to the ACO's historical benchmark.

In a dynamic healthcare environment, ACO participants may experience CHOWs and/or subsequent TIN changes during the performance year that affect their ability to continue in the Shared Savings Program. ACOs and ACO participants have requested that we establish a process whereby an ACO participant[401] that experiences a CHOW resulting in a surviving Medicare enrolled TIN with no prior Medicare billing claims history can be submitted by the ACO for CMS to review during the performance year.

As of January 1, 2025, there are 477 ACOs participating in the Shared Savings Program with more than 15,000 ACO participant TINs and 650,000 ACO providers and suppliers who have agreed to participate in ACOs. Due to the volume of data that we utilize to operationalize the Shared Savings Program, allowing for frequent or high volumes of changes to occur to an ACO's certified participant list during a performance year can increase the risk of errors, as well as uncertainty surrounding what data is utilized to produce a report. Additionally, it is important to ensure a degree of finality to reports for CMS and for ACOs to use during their participation in the Shared Savings Program and not allow data to constantly change. Therefore, it is important to limit the circumstances in which we allow ACOs to

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[401] A "certified ACO participant" means "an ACO participant that an ACO has listed on the ACO's certified ACO participant list." *See* 425.118(a)(3): "The ACO must certify the submitted lists in accordance with § 425.302(a)(2)."

modify their certified ACO participant lists during a performance year, as well as the operational processes we allow to account for changes to occur during the performance year.

(2) Allow Modifications to the Certified ACO Participant List for ACO Participant CHOWs During a Performance Year

As we described in the CY 2026 PFS proposed rule (90 FR 32660 through 32661), we recognize that requiring ACOs to wait until the upcoming change request cycle each performance year to update their certified ACO participant list to reflect an ACO participant's CHOW can, in some cases, present operational difficulties for ACOs. This gap may interfere with an ACO's ability to provide coordinated care to an ACO participant's patient population and negatively impact the ACO's participation in the Shared Savings Program. To account for such scenarios and to support ACOs' participation, effective January 1, 2026, we proposed ACOs that experience certain ACO participant CHOWs outside of the change request cycle must update their certified ACO participant list to reflect such ACO participant's CHOW. We proposed that this would apply to instances in which an ACO participant has undergone a CHOW resulting in a change to its Medicare enrolled TIN whereby the surviving Medicare enrolled TIN has no Medicare billing claims history. We explained that without the ability to report an ACO participant's CHOW and effectuate a change in the ACO's participant list during the performance year, the ACO may be unable to provide coordinated care to an ACO participant's patient population, which may cause the ACO's beneficiary count to fall below 5,000. An ACO participant change in ownership that reduces the ACO's number of assigned beneficiaries could constitute a significant change (as described at § 425.214) for the ACO, adversely affecting the ACO's participant agreement and jeopardizing the ACO's continued participation in the Shared Savings Program. We noted that, as described at § 425.214(a)(3), a significant change occurs when an ACO is no longer able to meet the eligibility or requirements of the Shared Savings Program.

To avoid confusion for ACOs and their ACO participants as well as to establish a clear and consistent process for the recognition of claims billed by the TIN of an ACO participant that has recently experienced a CHOW, we proposed to add new paragraph § 425.118(b)(3) to require an ACO to submit to CMS for review an ACO participant change request for a CHOW resulting in a change to the ACO participant's Medicare enrolled TIN whereby the surviving Medicare enrolled TIN has no Medicare

billing claims history in a form and manner set by CMS. We proposed to require an ACO to submit an ACO participant change request for a CHOW resulting in a change to the TIN throughout the performance year, no later than 30 days after the CHOW and outside of the change request cycle. We proposed that this requirement be limited to instances where the surviving TIN is newly enrolled in PECOS with no prior Medicare billing claims history to limit program disruption such as adversely affecting quality performance. We proposed at § 425.118(b)(3) that if CMS approves the change request containing a new ACO participant TIN, the ACO participant list would be updated in the form and manner specified by CMS. We proposed that CMS would have sole discretion whether to approve the ACO participant change request for a CHOW.

In alignment with proposed § 425.118(b)(3) and (b)(4)(iii) and upon CMS approval of the change request submitted with the TIN, we would adjust the ACO's assignment, performance year financial calculations, and the requirement that the ACO must submit quality data as described at §§ 425.508 and 425.510 for the applicable performance year on behalf of eligible professionals that bill under the TIN of an ACO participant. We would process these adjustments during the applicable Quality Payment Program (QPP) snapshot dates for the relevant Performance Period. The adjustments would reflect the addition, to the ACO participant list, of the surviving Medicare enrolled TIN with no prior Medicare billing claims history as a result of a CHOW. The adjustment would reflect the addition as the changes become effective during the performance year.

While we considered proposing to allow ACOs to submit all change of ownership requests outside of the change request cycle, we proposed limiting the out-of-cycle change of ownership requests to those ACO participant TINs without a prior Medicare billing claims history to avoid large discrepancies between the benchmark year patient population and the performance year patient population. To mitigate any disruptions in program calculations, we proposed to require that the surviving Medicare enrolled TIN have no Medicare billing claims history, meaning that the TIN does not have any paid claims for prior benchmark or performance years. We noted that this proposed change would not apply to a CHOW in which a TIN is absorbed into an existing TIN and the surviving TIN has prior Medicare billing claims history. Approval of the change request would not allow prior claims from the certified ACO participant TIN to be reprocessed under the surviving ACO participant TIN. Additionally,

we noted that this proposal would mitigate operational impacts, including determining expenditures used in financial reconciliation, determining an ACO's quality sample, and producing quarterly and annual reports.

We proposed to incorporate the ACO participants' surviving Medicare enrolled TINs with no prior Medicare billing claims history into the ACO's assignment, historical benchmark, performance year financial calculations, or the obligation of the ACO to report quality data on behalf of eligible professionals that bill under the TIN of an ACO participant, when processed during applicable QPP snapshot dates for the relevant Performance Period, during the performance year in which they are approved (§ 425.118(b)(4)(iii)). Effectuating an ACO participant change request for a CHOW resulting in a surviving Medicare-enrolled TIN with no prior Medicare billing claims history during the performance year could prevent an ACO participant from losing their status to participate in an ACO. We explained that this proposal, if finalized, would support such ACO participant's ability to retain its assigned beneficiaries and facilitate the provision of high-quality, value-based, evidence-based care.

In the CY 2026 PFS proposed rule (90 FR 32661 through 32662), we described our consideration of the operational impact of our proposal at § 425.118(b)(4)(iii). For example, the Quality Payment Program (QPP) updates eligibility data at multiple points throughout the year to assist ACOs in planning their Shared Savings Program participation. The QPP updates are based on past and current Medicare Part B claims and PECOS data. The Shared Savings Program sends ACO participant files to QPP, which then applies specific criteria to inform ACO eligibility reports. We review Alternative Payment Model (APM) participation four times for every performance year for clinicians and practices that are members of APMs (each review is called a "snapshot"). The first three snapshots are processed using the most current data available at the time. For CMS to meet operational processes such as QPP Determinations and APM Incentive Payments, ACOs would need to submit a change request in sufficient time for CMS to review, approve, and the ACO to certify, the revised ACO participant list without affecting annual adjustments under proposed § 425.118(b)(4)(iii). We noted that we will make available the operational considerations each PY to ensure ACOs are aware of the schedule considerations impacting the QPP Determination and APM Incentive Payments schedule.

Additionally, we noted that under proposed § 425.118(b)(4)(iii), CMS would then adjust the ACO's assignment, financial calculations, and the requirement for submission of quality data at § 425.508 and § 425.510 on behalf of eligible professionals that bill under the TIN of an ACO participant to reflect the addition of entities to the ACO participant list as they become effective during the performance year. This would be accomplished by providing ACOs with a mechanism to report an ACO participant CHOW that resulted in a new ACO participant TIN with no prior claims history on their certified ACO participant list and requiring that ACOs submit supporting documentation in the form and manner specified by CMS under proposed § 425.118(b)(3).

As described in the CY 2026 PFS proposed rule (90 FR 32662), we proposed to redesignate the current § 425.118(b)(3) as § 425.118(b)(4) and add a new § 425.118(b)(3) and (b)(4)(iii). We proposed to add new § 425.118(b)(3) to require an ACO to submit notice and supporting documentation according to the form and manner specified by CMS to demonstrate that a CHOW resulting in a change to the Medicare enrolled TIN has taken place. This supporting documentation would include information and material currently collected by CMS during the annual change request cycle when an ACO participant has merged with or been acquired by another entity.

We explained that should we finalize our proposals for § 425.118(b)(3) and (b)(4)(iii), we would provide additional guidance on the types of documentation that would suffice to meet the form and manner requirements. We noted that this supporting documentation could include a bill of sale, joinder agreement, or other legal document demonstrating a CHOW resulting in a new Medicare-enrolled TIN. Documentation demonstrating the surviving Medicare enrolled TIN with no prior Medicare billing claims history could also include documentation from the Internal Revenue Service (IRS) or from a state's Secretary of State (for example, IRS W-9, Employer Identification Number registration, or TIN assignment notice), or an affidavit explaining the CHOW resulting in the surviving Medicare enrolled TIN and confirming reassignment from the original ACO participant TIN to the surviving ACO participant TIN. We explained that this could include an attestation from the ACO that all the providers and suppliers that previously assigned their right to receive Medicare payment to the original ACO participant entity's TIN have reassigned such right to the surviving Medicare enrolled TIN with no prior

Medicare billing claims history for the identified ACO participant and will be added to the ACO provider/supplier list within 30 days in accordance with § 425.118(a)(4).

We proposed that the change have an effective date of January 1, 2026. We explained that we anticipate this approach would allow some ACOs to remain in the Shared Savings Program without interruption by continuing to utilize ACO participants who may have experienced a CHOW resulting in a surviving Medicare enrolled TIN with no prior Medicare billing claims history.

We sought comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters expressed broad support—or general support with additional recommendations—for the proposal to require an ACO to submit a change request to CMS and update the ACO participant list outside of the annual change request cycle when an ACO participant undergoes a CHOW that results in a surviving Medicare enrolled TIN with no prior Medicare billing claims history. Many commenters appreciated the flexibility the new provisions would provide and agreed that they would allow ACO participants to continue participating in the ACO without interruption, ultimately retaining attribution and continuity of care for beneficiaries when ACO participants' TINs change outside of the annual change request cycle. Several commenters encouraged CMS to ensure reporting requirements are easy to complete to limit any added burden on providers and staff, particularly for low-revenue ACOs.

Response: We appreciate the commenters' support for this proposal. CMS intends to develop a process for reporting a CHOW that meets program requirements while limiting operational burden for ACOs and providers.

Comment: A few commenters recommended that CMS extend the time period in which ACOs must notify CMS of CHOWs from 30 days to 45 or 60 days, stating that it might be difficult for an ACO participant to notify an ACO of a CHOW and for the ACO to then notify CMS of the CHOW. Commenters stated extending the notice window would ensure that any potential changes or modifications could be made without disruption to the ACO.

Response: We understand that ACOs must rely on ACO participants to report CHOWs before the

ACO can report them to CMS. However, we believe ACOs should be communicating regularly with their ACO participants and should generally be aware of an ACO participant's potential CHOW prior to the CHOW occurring. Additionally, we believe 30 days is important to help support ACO participants to continue participating in the ACO without interruption, ultimately retaining attribution and continuity of care for beneficiaries. We believe that 30 days is adequate time for an ACO to notify CMS once an ACO participant's CHOW has occurred and will maintain the 30-day requirement, which is consistent with existing reporting requirements in § 425.118(c).

Comment: A few commenters recommended that the changes be expanded to allow newly enrolled TINs owned by an existing ACO participant and/or the parent company of the ACO to be added outside of the change request cycle. The commenters suggested CMS leverage an ownership check of TINs when an ACO is flagged as merged or acquired. Another commenter suggested expanding the policy to also apply to CHOWs where there is no change in TIN.

Response: We must balance providing ACOs with additional flexibilities and maintaining operational stability of the program. At this time, we are limiting mid-year changes to the ACO participant list to changes stemming from an ACO participant's CHOW that has resulted in a change to its Medicare enrolled TIN, whereby the surviving TIN has no prior Medicare billing claims history, to avoid negative impacts to program operations, including assignment and benchmarking. For situations where there is no change in TIN, the relevant TIN remains on the ACO participant list and any additional changes can continue to be reported through the annual change request cycle.

After consideration of public comments, we are finalizing our proposals beginning January 1, 2026. Specifically, we are redesignating the current § 425.118(b)(3) as § 425.118(b)(4) and adding a new § 425.118(b)(3) and (b)(4)(iii). We are adding new § 425.118(b)(3) to require that no later than 30 days after an ACO participant has undergone a CHOW that has resulted in a change to its Medicare enrolled TIN, whereby the surviving Medicare enrolled TIN has no Medicare billing claims history, the ACO must submit a change request to CMS. This will allow ACOs to update their certified ACO participant list with a TIN newly enrolled in PECOS with no prior Medicare billing claims history, for an ACO participant that experiences a CHOW during the performance year and outside of the annual change request cycle. We are adding new § 425.118(b)(3)(i) to require an ACO to submit the change request and supporting

documentation according to the form and manner specified by CMS. We reiterate that we will provide guidance on the types of supporting documentation that will suffice. We are adding new § 425.118(b)(3)(ii), under which CMS has sole discretion to approve the change request, and if CMS approves the change request, the ACO participant TIN is updated in the ACO participant list in the form and manner specified by CMS. In alignment with changes approved under new paragraph (b)(3), we are adding new § 425.118(b)(4)(iii), under which CMS will adjust the ACO's assignment, performance year financial calculations, and the requirement that the ACO submit quality data under § 425.508 and § 425.510 on behalf of eligible professionals that bill under the TIN of an ACO participant. When processed during applicable Quality Payment Program snapshot dates for the relevant Performance Period, the adjustment includes the surviving Medicare enrolled TIN with no Medicare billing claims history on the ACO participant list as the change becomes effective during the performance year.

b. SNF Affiliate Change of Ownership (CHOW) Scenarios

(1) Background

The Medicare Skilled Nursing Facility (SNF) benefit applies to beneficiaries who require a short-term intensive stay in a SNF and skilled nursing and/or skilled rehabilitation care. Pursuant to section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days to be eligible for Medicare coverage of inpatient SNF care. This requirement is referred to as the SNF 3-Day Rule. Section 1899(f) of the Act permits the Secretary to waive certain payment or other program requirements necessary to carry out the Shared Savings Program. Specifically, CMS has used the authority under section 1899(f) to waive section 1861(i) of the Act to allow coverage of certain SNF services that are not preceded by a qualifying 3-day inpatient hospital stay. The Shared Savings Program's SNF 3-day rule waiver waives the requirement for a 3-day inpatient hospital stay prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries if certain conditions are met.

The SNF 3-day rule waiver at § 425.612(a)(1) allows for Medicare payment for otherwise covered SNF services when ACO providers/suppliers participating in ACOs participating under a two-sided model admit eligible beneficiaries, or certain excluded beneficiaries during a grace period, to an eligible SNF affiliate without a 3-day prior inpatient hospitalization. All other provisions of section

1861(i) of the Act and regulations regarding Medicare Part A post-hospital extended care services continue to apply. This waiver became available starting January 1, 2017, and all ACOs participating under, or that apply to participate under, Levels C-E of the BASIC track or under the ENHANCED track are eligible to apply for the waiver.

As we explained in the CY 2026 PFS proposed rule (90 FR 32662), it is important to note that the Shared Savings Program SNF 3-day rule waiver does not create a new benefit or extend Medicare SNF coverage to patients who could be treated in outpatient settings or who require long-term custodial care. Also, the SNF 3-day rule waiver does not restrict a beneficiary's choice of provider or supplier. A beneficiary continues to have the option to seek care from any Medicare FFS provider or supplier, including from a SNF or other facility that is not an affiliate of an ACO participating in the Shared Savings Program. If a beneficiary that is assigned to an ACO chooses to receive care from a SNF or other facility that is not an affiliate of the ACO, normal Medicare requirements apply, including the requirement for a 3-day inpatient hospitalization. The SNF 3-day rule waiver is intended to provide ACOs that are participating in certain performance-based risk tracks with additional flexibility to increase quality and decrease costs. As described at § 425.612(d)(2), CMS monitors and audits the use of the SNF 3-day rule waiver in accordance with § 425.316.

As part of the 3-day rule waiver supplemental application information requirements, at § 425.612(a)(1)(i)(B), ACOs must provide to CMS the list of SNFs with whom the ACO will partner along with executed SNF affiliate agreements between the ACO and each listed SNF. The SNF affiliate agreement with the ACO includes all individual SNFs identified by a CMS Certification Number (CCN) under the Medicare-enrolled SNF TIN that agree to partner with the ACO for purposes of a SNF 3-day rule waiver. The SNF 3-day rule waiver enables eligible SNFs to admit eligible beneficiaries to their SNF without a prior 3-day inpatient hospitalization. To identify an eligible SNF for purposes of a SNF 3-day rule waiver, the SNF's Medicare enrolled TIN and CCN must appear on the SNF affiliate list.

To have and maintain a SNF 3-day rule waiver, an ACO must have at least one approved SNF on its SNF affiliate list to meet the requirements of § 425.612(a)(1)(i)(B). Similar to the certified ACO participant list, ACOs can submit modifications to their SNF affiliate list in the form and manner

specified by CMS (currently submitted during the annual change request cycle), and approved additions to the list become effective on January 1 of the following performance year.

Operationally, the Shared Savings Program does not provide a mechanism by which an ACO can add a new TIN to its SNF affiliate list outside of the annual change request cycle, including in situations where a SNF affiliate experiences a CHOW resulting in a change to the Medicare-enrolled TIN. ACOs and SNF affiliates may encounter the same CHOW scenario as described in section III.F.3.a. of this final rule for ACO participants. If a SNF affiliate experiences a CHOW resulting in a change to the Medicare-enrolled TIN, it can no longer admit eligible beneficiaries without a prior 3-day inpatient hospitalization due to the change in Medicare enrollment and our current operational processes for receiving and reviewing SNF affiliate list modifications on an annual basis.

(2) Allow Modifications to the SNF Affiliate List for SNF Affiliate CHOWs During a Performance Year

As we described in the CY 2026 PFS proposed rule (90 FR 32663), ACOs have requested that we establish a mechanism to report a CHOW which results in a change in the Medicare-enrolled TIN for an approved SNF affiliate, which can be reviewed and effectuated by CMS during the performance year. This would enable the SNF affiliate to continue to participate with the ACO in the SNF 3-day rule waiver during the performance year and not have to wait until the next change request cycle to notify CMS of the change to the Medicare-enrolled TIN for the approved SNF affiliate.

As we explained in the CY 2026 PFS proposed rule, we recognize that requiring ACOs to wait until the upcoming change request cycle each performance year to update their SNF affiliate list to reflect an SNF affiliate's CHOW can interrupt ACO operations. This gap may prevent an ACO from utilizing a SNF affiliate that has undergone a CHOW resulting in a change in Medicare-enrolled TIN for the approved SNF affiliate under the SNF 3-day rule waiver. Therefore, we proposed to amend § 425.612(a)(1)(i)(B) by moving the text to § 425.612(a)(1)(i)(B)*(1)* and revising it to specify that the list of SNFs must include the Medicare enrolled TIN and the CCN of each SNF with whom the ACO will partner, along with executed written SNF affiliate agreements between the ACO and each listed SNF. We proposed this revision to ensure that we can link the SNF CCN with the correct Medicare enrolled TIN. We also proposed adding § 425.612(a)(1)(i)(B)*(2)* to require ACOs to notify CMS no later than 30 days after the change of ownership of a SNF affiliate, identified in accordance with paragraph (a)(1)(i)(B)(*1*),

that has resulted in a change to the Medicare enrolled TIN of the SNF affiliate in the form and manner specified by CMS.

We proposed to require an ACO to submit such a notification at any point during the performance year that is 30 days after the change in ownership, which would include times outside of the change request cycle. This proposed change is limited to a change of ownership of a SNF affiliate that has resulted in a change to the Medicare-enrolled TIN, as the CHOW affects the SNF affiliate's ability to participate under the 3-day rule waiver. This proposed change would not allow an ACO to add a new SNF affiliate as the result of a CHOW. Additionally, we proposed to require an ACO to submit supporting documentation demonstrating the change in SNF affiliate TIN similar to that described for an ACO participant TIN CHOW (see section III.F.3.a. of this final rule), and in accordance with the form and manner specified by CMS. Supporting documentation could include information from the Internal Revenue Service (IRS) or the State's Secretary of State, IRS W-9, Employer Identification Number registration, TIN assignment notice, or an affidavit explaining the TIN change and confirming reassignment from the original SNF affiliate TIN to the new SNF affiliate TIN.

As we described in the proposed rule (90 FR 32663), following CMS approval of the ACO's change request under proposed § 425.612(a)(1)(i)(B), we would send an updated list of approved SNF affiliates to the Medicare Administrative Contractor (MAC). The MAC would process the change; however, an ACO would still need to confirm with its MAC that the change has been fully effectuated. We explained that our proposal does not impact assignment of beneficiaries to an ACO and therefore would not impact the ACO beneficiaries eligible for the SNF 3-day rule waiver. It would only impact the SNFs that are approved as affiliates to provide care without the required three-day inpatient hospital stay.

A recent report released by the Assistant Secretary for Planning and Evaluation (ASPE) found frequent changes of ownership in hospitals and SNFs between 2016 and 2021, reporting that more than 3,200 SNFs experienced a CHOW.[402] Requiring an ACO to submit updates to its SNF affiliate list during the performance year if one of its SNF affiliates experiences a CHOW requires clear policies and procedures associated with such changes. It is important to avoid a scenario where CMS or an ACO is

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[402] ASPE, Research Brief, *Changes in Ownership of Skilled Nursing Facilities from 2016 to 2021: Variations by Size, Occupancy Rate, Penalty Amount, and Type of Ownership* (May 10, 2024), available at https://aspe.hhs.gov/sites/default/files/documents/9c4c5c8f2d48309c83e87f544b1aed90/snf-ownership-changes-variations.pdf.

unclear whether a SNF is approved to use the SNF 3-day rule waiver and when that information has been shared with the MAC for proper claims processing. Therefore, it is important to limit the circumstances which allow for ACOs to modify their SNF affiliate lists during a performance year outside of the scenario of a CHOW.

We explained that overall, the proposal to allow modifications to the SNF affiliate list for SNF affiliate CHOWs resulting in a change to the TIN would benefit CMS, ACOs and their SNF affiliates, and beneficiaries. This change would support continuous operations that improve access to quality care and care coordination as beneficiaries transition to a SNF. Historically, SNFs that undergo a CHOW that result in a change to the TIN have been unable to continue participation in the SNF 3-day rule waiver until the next change request cycle. Our proposal, if finalized, would ensure more timely access to skilled nursing care for Medicare beneficiaries.

We proposed that the change have an effective date of January 1, 2026. We explained that we anticipate this approach would provide ACOs the flexibility to continue to utilize the SNF 3-day rule waiver for SNF affiliates who may have experienced a CHOW resulting in a change to the TIN.

We sought comments on our proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed broad support—or general support with additional recommendations—for the proposal to require an ACO to notify CMS no later than 30 days after a SNF affiliate's CHOW when the CHOW results in a change to the SNF affiliate's Medicare enrolled TIN. Commenters noted that the flexibility permitted by this policy would improve beneficiary care by maintaining access to the 3-day SNF waiver. Several commenters encouraged CMS to ensure reporting requirements are easy to complete, to limit any added burden on providers and staff.

Response: We appreciate the commenters' support of this proposal. CMS intends to develop a process for reporting SNF affiliate CHOWs that meets program requirements while limiting operational burden for ACOs and SNFs.

Comment: A few commenters recommended that CMS extend the time period in which ACOs must notify CMS of SNF affiliate CHOWs from 30 days to 45, 60, or 90 days, stating that it might be

difficult for a SNF affiliate to notify an ACO of a CHOW and for the ACO to then notify CMS of the CHOW within the 30-day period. Commenters stated extending the notice window would ensure that any potential changes or modifications could be made without disruption to the ACO and improve continuity of care.

Response: We understand that ACOs must rely on SNF affiliates to report CHOWs before the ACOs are able to report to CMS. However, we believe ACOs should be communicating regularly with their SNF affiliates and should generally be aware of a potential SNF affiliate CHOW prior to the CHOW occurring. We believe that 30 days is adequate to notify CMS once the CHOW has occurred and will maintain the 30-day requirement, which is consistent with other time periods for ACOs to notify CMS of changes to the ACO provider/supplier list in § 425.118(c).

Comment: A commenter raised a concern about the use of the term "CHOW," believing that it only applies in situations where no TIN change occurs, citing the regulation at 42 CFR § 489.18(c), which states: "When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner."[403]

Response: We appreciate this commenter's concern. However, while the regulation states the existing provider agreement will "automatically" be assigned to the new owner, this does not mean that it is required to be assigned to the new owner. If the purchaser elects not to accept a transfer of the provider agreement, then the old agreement should be terminated, and the purchaser is considered a new applicant.[404] The CHOW term applies in these scenarios.

Comment: A commenter opposed the change, stating that the current requirement protects beneficiaries, as nursing home ownership and operations can impact quality of care. They believe that the elimination of this requirement would undo, to some extent, the limited but significant progress made by CMS' final rule addressing nursing home ownership and disclosable parties. They believe CMS' current requirement for ACOs to await the change request cycle each performance year to update an ACO's SNF affiliate list serves an important protective role for Medicare beneficiaries.

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[403] *See* 42 CFR 489.18(c).
[404] *State Operations Manual (*V 202) (June 2020), *§ 3210.5A, "New Owner Refuses to Accept Assignment of the Previous Owner's Provider Agreement",* available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c03pdf.pdf.

Response: We appreciate this commenter's concern regarding beneficiary quality of care and SNF ownership. However, we do not believe that our proposal regarding mid-year updates to the SNF affiliate list significantly impacts decision making when organizations undergo a CHOW. Our process also does not impact any recent CMS regulation related to mergers, acquisitions, consolidations, and changes of ownership for hospitals and nursing homes enrolled in Medicare. Our policy simply requires the ACO to update its SNF affiliate list after a SNF affiliate CHOW occurs. We believe this ultimately will improve continuity of care, as beneficiaries will maintain access to the SNF 3-day rule waiver.

After consideration of public comments, we are finalizing our proposal beginning January 1, 2026 to require ACOs to report certain changes that occur during the performance year to SNF affiliates on the ACO's SNF affiliate list. Specifically, we are finalizing a requirement for ACOs to notify CMS no later than 30 days after a SNF affiliate's CHOW if the CHOW resulted in a change to the SNF affiliate's Medicare enrolled TIN. We are amending § 425.612(a)(1)(i)(B) by moving the text to § 425.612(a)(1)(i)(B)(*1*) and revising it to specify that the list of SNFs must include the Medicare-enrolled TIN and the CCN of the SNFs with whom the ACO will partner along with executed written SNF affiliate agreements between the ACO and each listed SNF. We are also adding § 425.612(a)(1)(i)(B)(*2*) to require ACOs to notify CMS no later than 30 days after the change of ownership of a SNF affiliate, identified in accordance with paragraph (a)(1)(i)(B)(*1*), that has resulted in a change to the Medicare enrolled TIN of the SNF affiliate in the form and manner specified by CMS. We are also finalizing the requirement, in § 425.612(a)(1)(i)(B)(*2*), that such notice and supporting documentation must be submitted in the form and manner specified by CMS.

4. ACO Eligibility and Related Financial Reconciliation Requirements

a. Overview

As we described in the CY 2026 PFS proposed rule (90 FR 32663), under the Shared Savings Program regulations, CMS "deems" an ACO to have initially satisfied the statutory requirement to have at least 5,000 assigned Medicare FFS beneficiaries (section 1899(b)(2)(D) of the Act), if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the three historical benchmark years as defined at § 425.110(a)(2). Since the start of the Shared Savings Program, we have denied the applications of ACOs applying to participate in the program if the number of assigned beneficiaries was

below 5,000 beneficiaries in any historical benchmark year. This policy was established to align with the statutory requirement and to ensure CMS is able to reliably and accurately assess ACO financial and quality performance. The purpose of the historical benchmark is to establish a fair and reliable baseline to compare with performance year expenditures in the calculation of an ACO's shared savings or losses. As an ACO's assigned beneficiary population decreases, the ability of CMS to reliably and accurately assess ACO financial and quality performance also decreases. In the November 2011 final rule (76 FR 67807 and 67808), we expressed the benefit of a 5,000-beneficiary minimum to maintain program eligibility and allow CMS to assess ACO financial and quality performance, while also planning a course of action for when an ACO falls below the 5,000-beneficiary minimum.

Furthermore, as we explained in the CY 2026 PFS proposed rule (90 FR 32664), CMS finalized the minimum savings rate (MSR) for ACOs with at least 5,000 assigned beneficiaries such that the MSR for each ACO would be based on increasing confidence intervals as the number of assigned beneficiaries increases (76 FR 67928 and 67929). At the same time, CMS recognized the higher uncertainty regarding expenditures for smaller ACOs and CMS' desire to encourage program participation by smaller ACOs. Accordingly, CMS set the confidence interval at 90 percent for ACOs with 5,000 beneficiaries assigned, resulting in an MSR of 3.9 percent for those ACOs. For ACOs with 20,000 and 50,000 assigned beneficiaries, CMS set the confidence interval at 95 percent and 99 percent, respectively, for those ACOs, resulting in MSRs of 2.5 percent and 2.2 percent (76 FR 67928). As ACO size increases from 5,000 to 20,000 assigned beneficiaries (or similarly from 20,000 to 50,000), CMS blends the MSRs between the two neighboring confidence intervals, resulting in the MSRs as shown in Table 6 of the November 2011 final rule (76 FR 67928).

Building on the November 2011 final rule, in the December 2018 final rule, CMS finalized a variable MSR and Minimum Loss Rate (MLR) for ACOs that fall below 5,000 beneficiaries in the performance year according to assigned beneficiary ranges and based on a confidence interval of 90 precent, as a way to better ensure that the program is rewarding or holding accountable ACOs for actual performance, not normal expenditure fluctuations (83 FR 67927) (§§ 425.605 and 425.610).

Although most ACOs are able to reach the 5,000 beneficiaries assigned minimum, we recognized that this requirement does prevent some applicants from participating in the Shared Savings Program.

Since the inception of the program, we have gained additional experience with the requirement to have 5,000 beneficiaries assigned in each benchmark year, and experience with how this requirement relates to the integrity and stability of financial performance calculations. This experience has provided additional information that shows we can both retain the financial integrity of benchmark calculations and ensure CMS can reliably and accurately assess ACO financial and quality performance while allowing for ACOs that have fewer than 5,000 beneficiaries assigned in their benchmark years to enter the program, if we implement additional safeguards that protect ACOs and the Trust Funds. As described in the CY 2026 PFS proposed rule (90 FR 32666), we proposed changes to the Shared Savings Program eligibility requirements to allow for participation by ACOs with a minimum of 5,000 assigned beneficiaries in their third benchmark year, even if the ACO has fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both. Further, we proposed safeguards to limit ACOs entering a new agreement period with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, at the time of application, to participate in the BASIC track (90 FR 32666 and 32667). We also proposed additional safeguards for ACOs with fewer than 5,000 assigned beneficiaries in any of their benchmark years, by applying an alternative performance payment limit and loss recoupment limit for these ACOs (90 FR 32667 through 32671) and excluding these ACOs from leveraging policies providing certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings (90 FR 32671).

b. ACO Eligibility Requirement

(1) Background

(a) Background on Assigned Beneficiary Minimum Requirement

Section 1899(b)(2)(D) of the Act requires participating ACOs to include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO and that, at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it under section 1899(c) of the Act in order to be eligible to participate in the Shared Savings Program.

In the November 2011 final rule (76 FR 67808), in alignment with the statutory requirement at section 1899(b)(2)(D) of the Act, CMS established that for an ACO to satisfy the requirement to have at least 5,000 assigned beneficiaries, the ACO must have 5,000 or more beneficiaries historically assigned to the ACO participants in each of the 3 benchmark years. See § 425.110(a)(2). We described the

importance of maintaining at least 5,000 assigned beneficiaries with respect to both the eligibility of the ACO to participate in the program and the ability of CMS to reliably and accurately assess ACO financial and quality performance. However, we also noted in that rule (76 FR 67807) that we understood circumstances may change during an ACO's agreement period, and that an ACO's assigned population may vary accordingly, and if the ACO falls below 5,000 beneficiaries during the agreement period, the ACO will be subject to compliance actions (described at §§ 425.216 and 425.218).

Additionally, in the November 2011 final rule (76 FR 67929), we finalized the MSR/MLR with a sliding scale that varies based on the number of beneficiaries assigned to the ACO from 5,000 up to 60,000. The largest ACOs with over 50,000 assigned beneficiaries had 99 percent confidence intervals. At the same time, CMS also recognized ACOs with the minimum 5,000 assigned beneficiaries must meet a higher MSR of 3.9 percent to be eligible for shared savings payments, based on a confidence interval of 90 percent (76 FR 67927).

In the CY 2025 PFS final rule (89 FR 98085 through 98086), we finalized a policy to sunset the requirement at § 425.110(b)(2) that CMS will terminate an ACO's participation agreement and determine that an ACO is not eligible to share in savings for that performance year if an ACO's assigned beneficiary population is not at least 5,000 by the end of the performance year specified by CMS in its request for a corrective action plan. We explained that this requirement could be sunset because the policy finalized in the December 2018 final rule (83 FR 67925 through 67929), to use a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO's assigned beneficiary population fell below 5,000 for the performance year, was effective in protecting both CMS and the ACO from inappropriate overpayments or underpayments and reduced the financial risk of allowing ACOs to continue to participate in the Shared Savings Program if they experience a reduction in assigned beneficiaries. As we have explained in prior rulemaking, the MSR/MLR protects against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than actual program performance (83 FR 67923 through 67926).

As we explained in the CY 2026 PFS proposed rule (90 FR 32664 and 32665), after gaining 13 years of experience administering the Shared Savings Program, including lessons learned from applying the requirement at section 1899(b)(2)(D) of the Act that "[a]t a minimum, the ACO shall have at least

5,000 such beneficiaries assigned to it […] in order to be eligible to participate in the ACO program," we have determined it is in the best interest of Medicare beneficiaries, the Trust Funds, and participating ACOs to modify the requirement at § 425.110(a)(2) so that it better supports the goals of the Shared Savings Program. As the program grows in experience, the programmatic guardrails can be changed to better incentivize ACOs, especially those that have successfully participated in the program, to participate in the program while maintaining CMS' ability to reliably and accurately assess ACO financial and quality performance. Historically, the 5,000 assigned beneficiary benchmark year minimum has been implemented across all benchmark years to assess an ACO's financial and quality performance. However, after reviewing historical data and program operations, we believe the 5,000-beneficiary benchmark year minimum can be applied to BY3 only, which provides the most recent data available prior to an ACO entering an agreement period, to maximize the goals and benefits of the Shared Savings Program.

As discussed in the CY 2026 PFS proposed rule (90 FR 32665), the 5,000-beneficiary benchmark year minimum applied across all benchmark years helps to ensure that CMS is able to reliably and accurately assess ACO financial and quality performance during the Shared Savings Program application process. However, this beneficiary threshold is most critical in assessing BY3. Specifically, during the application cycle, CMS makes available to all currently participating ACOs and all applicant ACOs estimates of the number of assigned beneficiaries for each of the three benchmark years. The BY3 assignment provided is based on the most recently available 24 months of Medicare beneficiary claims data. The application cycle occurs during the calendar year that corresponds to BY3, and we run assignment based upon the 24 months prior to the end date of the most recent quarter available. Therefore, BY3 is the most current assignment run we produce during the application cycle for assessing the number of assigned beneficiaries an ACO has at the time they are applying to participate in the Shared Savings Program.

(b) Background on Track Specific Requirements for Participation Options

With the December 2018 final (83 FR 67831 through 67841), we finalized the availability of participation options under the BASIC track and ENHANCED track for ACOs entering an agreement period beginning on July 1, 2019, and in subsequent years. We refer readers to the CY 2026 PFS proposed rule (90 FR 32648 through 32651) for background information on Shared Savings Program

participation options. The BASIC track and the ENHANCED track offer differing levels of risk and potential reward. See §§ 425.600(a)(3) to (4), 425.605, and 425.610. In general, an ACO that meets or exceeds its MSR, and otherwise qualifies for a shared savings payment, shares in savings at a sharing rate specified by the ACO's participation track (and level, if applicable), not to exceed a performance payment limit (a percentage of the ACO's updated historical benchmark). There is a limited exception for eligible low revenue ACOs participating under the BASIC track, under which an ACO that does not meet the MSR requirement but meets other criteria may qualify for a shared savings payment, at a lower sharing rate, in accordance with § 425.605(h). An ACO under a two-sided model that meets or exceeds its MLR shares in losses at a shared loss rate specified by the ACO's participation track (and level, if applicable), not to exceed a loss recoupment limit (a percentage of the ACO's updated historical benchmark). In summary:

- The BASIC track (see §§ 425.600(a)(4) and 425.605) includes a "glide path" from one-sided model Levels A and B to incrementally higher levels of performance-based risk under Levels C, D, and E.

++ Under Levels A and B of the BASIC track, an ACO may share in savings at a sharing rate of up to 40 percent (§ 425.605(d)(1)(i)(A) and (d)(1)(ii)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(i)(B) and (d)(1)(ii)(B)).

++ Under Level C of the BASIC track, an ACO may share in savings at a sharing rate of up to 50 percent (§ 425.605(d)(1)(iii)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(iii)(B)), and may share in losses at a loss sharing rate of 30 percent (§ 425.605(d)(1)(iii)(C)), not to exceed 2 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 1 percent of updated benchmark (§ 425.605(d)(1)(iii)(D)).

++ Under Level D of the BASIC track, an ACO may share in savings at a sharing rate of up to 50 percent (§ 425.605(d)(1)(iv)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(iv)(B)), and may share in losses at a loss sharing rate of 30 percent (§ 425.605(d)(1)(iv)(C)), not to exceed 4 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 2 percent of updated benchmark (§ 425.605(d)(1)(iv)(D)).

++ Under Level E of the BASIC track, an ACO may share in savings at a sharing rate of up to 50 percent (§ 425.605(d)(1)(v)(A)), not to exceed 10 percent of updated benchmark (§ 425.605(d)(1)(v)(B)),

and may share in losses at a loss sharing rate of 30 percent (§ 425.605(d)(1)(v)(C)), not to exceed 8 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 4 percent of updated benchmark (§ 425.605(d)(1)(v)(D)). The loss recoupment limit is the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (42 CFR § 414.1415(c)(3)(i)(A)) capped at 1 percentage point higher than the expenditure-based nominal risk amount (§ 414.1415(c)(3)(i)(B)).

- Under the ENHANCED track (§§ 425.600(a)(3) and 425.610), with the highest level of risk and potential reward under the Shared Savings Program, an ACO may share in savings at a sharing rate of up to 75 percent (§ 425.610(d)), not to exceed 20 percent of updated benchmark (§ 425.610(e)), and may share in losses at a loss sharing rate not less than 40 percent and not to exceed 75 percent (§ 425.610(f)), capped at 15 percent of updated benchmark (§ 425.610(g)).

Currently, CMS allows ACOs to choose to participate in either the BASIC track or ENHANCED track (see § 425.600(a), and see also § 425.226(a)), provided the ACO meets the eligibility criteria set forth in 42 CFR part 425 subpart B. An ACO must select a Shared Savings Program participation option for which CMS determines it is eligible under § 425.600(g). An ACO entering the BASIC track may elect to start at any level for which it is eligible, based on its experience with performance-based risk Medicare ACO initiatives (refer to § 425.600(a)(4)(i)(C)(1) and (g)). During the application cycle, CMS conducts a prescreening assessment to evaluate an ACO's eligibility for its selected level. The evaluation includes verifying whether the ACO complies with general program requirements and the ability of the ACO to take on risk (83 FR 41806). *See* §§ 425.202(a) and 425.204. Also, part of this check assesses the ACO's ability to provide an adequate repayment mechanism for shared losses if the chosen track is two-sided (§ 425.204(f)(3)(i)). CMS may deny an ACO applicant's application if the ACO applicant fails to satisfy the requirements of the Shared Savings Program on the basis of information contained in and submitted with the application per § 425.206(a)(1).

(2) Revisions

(a) Allow ACOs to Enter the Shared Savings Program with Fewer than 5,000 Assigned Beneficiaries in BY1, BY2, or Both

As we described in the CY 2026 PFS proposed rule (90 FR 32665 and 32666), the requirement in

§ 425.110(a)(2) for an applicant ACO to have at least 5,000 assigned Medicare FFS beneficiaries in each of the 3 historical benchmark years is the most common reason we deny ACO applicants' applications. In evaluating potential changes to this eligibility policy at § 425.110(a), we considered ways to increase flexibility regarding the minimum number of assigned beneficiaries required in benchmark years, to continue to support new and previously successful renewing and re-entering ACOs participating in the Shared Savings Program, while minimizing adverse financial impacts to ACOs and the Shared Savings Program that may arise from program participation by ACOs with fewer than 5,000 beneficiaries assigned in one or more historical benchmark years.

Consequently, in the CY 2026 PFS proposed rule we proposed to amend our requirements at § 425.110(a)(2) to specify that, for agreement periods beginning on or after January 1, 2027, ACOs applying to enter a new agreement period would be required to have at least 5,000 assigned beneficiaries in the ACO's BY3 but could be under 5,000 assigned beneficiaries in BY1, BY2, or both. Currently, on the basis of § 425.110(a)(2), we deny an applicant ACO's application to enter or renew its participation in the program if the ACO would be assigned fewer than 5,000 beneficiaries in any of benchmark years 1 to 3. Under the policy we proposed, ACOs would not be prevented, on the basis of § 425.110(a)(2), from entering the program if they are below 5,000 assigned beneficiaries in BY1, BY2, or both. We proposed to sunset the current policy regarding ACOs with fewer than 5,000 assigned beneficiaries in any of the benchmark years after December 31, 2026, and make this change applicable for ACOs applying to enter new agreement periods beginning January 1, 2027, and for subsequent agreement periods. We proposed to apply this modified approach for agreement periods beginning January 1, 2027, instead of January 1, 2026, because the application cycle for agreement periods starting January 1, 2026, was already underway when the CY 2026 PFS proposed rule appeared in the **Federal Register**, and this proposal would not be finalized until November 2025, by which point we will be preparing to grant or deny applications for agreement periods starting January 1, 2026, in early December.[405]

We explained our belief that this proposal is consistent with the statutory requirements at section 1899(b)(2)(D) of the Act that "[a]t a minimum, the ACO shall have at least 5,000 [Medicare FFS]

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[405] See Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Period Beginning on January 1, 2026, available at https://www.cms.gov/files/document/key-application-dates-and-deadlines-2026.pdf.

beneficiaries assigned to it under subsection (c) in order to be eligible to participate in the ACO program," because the proposal requires that an ACO must meet the 5,000-beneficiary minimum before entering an agreement period (90 FR 32666). While the statute established this requirement, subsequent rulemaking defines its specific implementation parameters such as in the benchmark years. We stated that this proposed update would align with the statutory requirement at section 1899(b)(2)(D) of the Act.

We further explained that, over the last several Shared Savings Program application cycles for ACOs entering a new agreement period, about 2 percent of ACO applicants on average were denied participation in the program due to the ACOs having fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, while still having more than 5,000 assigned beneficiaries in BY3 and meeting all other program eligibility requirements (90 FR 32666). Additionally, the proposed revisions would allow new, renewing, and re-entering ACOs that have been successful in the program previously and that fall under 5,000 assigned beneficiaries in BY1 and/or BY2 to continue to participate in the Shared Savings Program as long as such ACOs meet all other Shared Savings Program requirements.

We stated this proposal would provide greater flexibility on the requirement to have 5,000 assigned beneficiaries in each benchmark year, but it also could introduce risk for both the ACO and the program (90 FR 32666). For example, as an ACO's assigned beneficiary population decreases, variability in the population's expenditures increases because a few beneficiaries with unusually high or unusually low expenditures could have a substantive impact on an ACO's overall expenditures. The reduction in the size of the ACO's assigned beneficiary population in benchmark years could result in variability in benchmark calculations that could cause shared savings payments or shared losses owed to be based on normal expenditure fluctuations, rather than reflect ACO performance in the program. Accordingly, we also proposed safeguards to address variability in calculations and to protect both ACOs and Medicare Trust Funds (90 FR 32664 through 32671).

We proposed to revise § 425.110 as follows. At § 425.110(a), we proposed to revise paragraph (2) by adding the introductory phrase, "For agreement periods beginning before January 1, 2027", to limit the timing of applicability of the provision.

We proposed adding new paragraph (3) to § 425.110(a) specifying that for agreement periods beginning on or after January 1, 2027, we determine whether an ACO has 5,000 or more beneficiaries

historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. We also proposed to specify under new § 425.110(a)(3) that we would use the most recent data available to estimate the number of assigned beneficiaries in the third benchmark year. Additionally, we proposed to specify in new § 425.110(a)(3)(i) through (ii) the following provisions in connection with our determination of whether an ACO has 5,000 or more assigned beneficiaries in its benchmark years.

- We would deem an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified at § 425.110(a)(1) if 5,000 or more beneficiaries are historically assigned to the ACO participants in the third benchmark year.
- If an ACO has fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, the ACO may only participate under the BASIC track in accordance with new § 425.600(h)(3) (90 FR 32648 through 32659 and 90 FR 32666 through 32667).

(b) Require an ACO with Fewer than 5,000 Assigned Beneficiaries in BY1, BY2, or Both to Participate only under BASIC Track

Providing greater flexibility around the requirement to have 5,000 assigned beneficiaries in BY1, BY2, or both may introduce risk to the program. In the CY 2026 PFS proposed rule (90 FR 32666), we explained that as an ACO's assigned beneficiary population decreases, variability in the population's average expenditures increases. The reduction in the size of the ACO's assigned beneficiary population in benchmark years could result in variability in benchmark calculations that could cause shared savings payments or shared losses owed to be based on normal variation in expenditures, rather than reflect ACO performance in the program. We proposed that if an ACO, when entering a new agreement period, is under the 5,000-beneficiary minimum in BY1, BY2, or both, but meets this requirement in BY3, the ACO may only enter an agreement period in the BASIC track, to reduce the potential risk to the ACO and to the Shared Savings Program that we described elsewhere in the CY 2026 PFS proposed rule (90 FR 32666).

We explained that we allow ACOs to choose to participate in either the BASIC track or ENHANCED track, as long as they meet all applicable eligibility criteria, including the requirements to participate under performance-based risk. *See* § 425.600(a)(4)(i)(C)(*4*), and (g). We apply eligibility

checks for an applicant ACO's track selection during the annual application cycle and communicate track eligibility to the ACO through the Participations Options Report. Under the proposed approach, during the application cycle, we would review an ACO's track selection in combination with its number of assigned beneficiaries in each benchmark year and provide information to the ACO about its participation options. ACOs would receive an opportunity to correct deficiencies and/or make updates or modifications to the ACO's change request(s) during two rounds of RFI (Request for Information) submission periods in Phase 1 of the application cycle. We would also provide a final disposition of an ACO's eligibility for program participation, and we would deny applicants from participation in the program if they do not meet all eligibility criteria.

We proposed that this change would be applicable for ACOs applying to enter new agreement periods beginning on or after January 1, 2027.

As described in the CY 2026 PFS proposed rule (90 FR 32669), an ACO with fewer than 5,000 assigned beneficiaries in one or both of benchmark years 1 and 2 could experience variability in benchmark calculations which could cause shared savings payments or shared losses owed to be based on normal expenditure fluctuations, rather than reflect actual program performance, because a small number of beneficiaries either with unusually high or unusually low expenditures could substantially affect the variability of the benchmark calculations. This proposal to limit ACOs in this situation to the BASIC track protects these ACOs from incurring a larger shared losses rate of up to 75 percent (see § 425.610(f)(4)), and it protects the Medicare Trust Funds from paying a larger shared savings rate of up to 75 percent (see § 425.610(d)(4)), which could result under the ENHANCED track, attributable to variability in benchmark calculations associated with ACOs with fewer than 5,000 assigned beneficiaries in one or both of benchmark years 1 and 2 rather than actual program performance.

As described in the CY 2026 PFS proposed rule (90 FR 32666), we proposed a related provision in new § 425.600(h)(3), applicable for agreement periods beginning on or after January 1, 2027, under which, if an ACO is determined to have fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, in accordance with § 425.110(a)(3) (as proposed to be revised), the ACO may only enter the BASIC track. As described in further detail in the CY 2026 PFS proposed rule (90 FR 32648 through 32659), under this proposed approach, an ACO may enter a level of

risk and potential reward under the BASIC track in accordance with the requirements of new § 425.600(h).

We sought comments on the proposals to allow ACOs to participate in the Shared Savings Program if they have fewer than 5,000 assigned beneficiaries in BY1, BY2, or both (but have at least 5,000 assigned beneficiaries in BY3) and the requirement that these ACOs may only enter an agreement period in the BASIC track.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters generally supported the proposed revision to allow ACOs to enter the Shared Savings Program with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both. A few commenters supported the revision because it recognizes operational realities and helps ensure program stability. Another commenter appreciated these proposed changes and thought that they would streamline ACO participation and measurement. An additional commenter agreed that this revision adds flexibility for ACOs that will support continuity of care for the beneficiaries they serve.

A large number of supportive commenters stated that the policy provides flexibility that will help new ACOs join the Shared Savings Program. Many advocated that community health centers are eager to continue to enter into value-based care agreements, and this proposal will open the door to allow more to embark on this endeavor. A few commenters stated that new, re-entering, and renewing ACOs that could not participate in the Shared Savings Program because of the requirement to have at least 5,000 assigned beneficiaries in BY1 and BY2 would now be able to begin or continue to participate in the program.

Several commenters noted that the flexibility of this policy will encourage broader participation in the Shared Savings Program, including by new entrants, by lowering barriers for Shared Savings Program entry. A commenter stated this flexibility will be important for new ACOs to join the Medicare Shared Savings Program, especially as meeting minimum beneficiary assignment thresholds may become harder as more beneficiaries move from Traditional Medicare to enrollment in a Medicare Advantage plan. Another commenter suggested that beneficiaries will benefit from this proposed change as ACOs will have greater flexibility to expand their assigned beneficiary populations and recruit clinicians to meet the needs of their beneficiaries. Some commenters mentioned that this will allow smaller ACOs with less

than 5,000 assigned beneficiaries the opportunity to participate in this program and therefore participate in value-based care, enabling ACOs to build their assigned beneficiary population over time without having their participation in the program jeopardized, with a commenter recommending that CMS continue to pursue additional policies and flexibilities that allow smaller ACOs to participate in the Shared Savings Program.

Additionally, many supportive commenters believe that the policy provides flexibility that will help current participants to continue to participate successfully in the Shared Savings Program. A couple of commenters thought the policy would help avoid unnecessary ACO participation agreement terminations due to dips in beneficiary assignment counts. A commenter appreciated CMS efforts to ensure that small, low revenue, and often physician-led ACOs can continue to participate in the Shared Savings Program. Another commenter supported the proposal because it provides needed flexibility and reflects a more practical approach to the variation in beneficiary assignment counts over time, particularly for smaller ACOs and those in regions with fluctuating Medicare populations.

Lastly, some commenters appreciated how the policy has the potential to support rural ACOs that face unique challenges in growing their patient base and who may not have 5,000 assigned beneficiaries in all three benchmark years. Several commenters noted that rural ACOs will benefit from greater flexibility, and that the proposal would allow for increased participation for rural ACOs in the Shared Savings Program. Another commenter appreciated how the policy allows for meaningful engagement and accountability by long-term care providers seeking to "engage in the full healthcare experience and risk for their residents and patients while aligning with CMS' vision".

Response: We thank commenters for their support.

Comment: Some commenters had concerns about requiring ACOs that enter the program with fewer than 5,000 assigned beneficiaries in BY1 or BY2 or both to participate in the BASIC track. A couple of the commenters described that they believed some of the requirements were "arbitrary" and would prevent smaller ACOs from participating in the ENHANCED track if they fall below 5,000 assigned beneficiaries during benchmark years 1 or 2. Further, the commenters indicated that for ACOs falling below 5,000 assigned beneficiaries in benchmark year 3, these ACOs would be unable to renew their participation agreement, and that these new restrictions would disproportionately harm rural and

underserved communities, where assigned populations are smaller and more prone to year-over-year fluctuations. Additionally, these commenters stated these changes would discourage the formation of new ACOs and penalize existing ACOs for changes outside their control, undermining the goal of the Shared Savings Program to expand access to coordinated, high quality care. Finally, these commenters concluded these proposed limitations would reduce opportunities for collaboration and shared savings, ultimately harming both providers and the Medicare program.

A commenter stated that limiting track options reduces ACOs' potential return on investment, which may lead some providers—particularly those without large beneficiary pools or financial reserves—to forgo participation altogether. The commenter stated this would be counterproductive to the agency's stated goal of broadening Shared Savings Program participation. A commenter stated they support CMS' efforts to reduce the barrier to entering the program by allowing ACOs with fewer than 5,000 beneficiaries for the first two benchmark years to participate, but the commenter urges CMS to reconsider limitations on these ACOs' participation options.

Response: We appreciate the commenters' concerns and recommendations. However, as we explained in the CY 2026 PFS proposed rule, and restated elsewhere in this section of this final rule, this proposal to limit ACOs in this situation to the BASIC track protects ACOs from incurring a larger shared losses rate of up to 75 percent (see § 425.610(f)(4)), and this proposal protects the Medicare Trust Funds from paying a larger shared savings rate of up to 75 percent (see § 425.610(d)(4)), which could result under the ENHANCED track. Accordingly, we believe this requirement is not arbitrary but rather reasoned. Our proposal would help mitigate the risk of paying substantial shared savings to an ACO where the savings are attributable to the variability in benchmark calculations rather than actual program performance as can be the case for ACOs with fewer than 5,000 assigned beneficiaries in one or both of benchmark years 1 and 2 that are susceptible to performance variability. We want to clarify that this provision requires ACOs with fewer than 5,000 assigned beneficiaries in one or both of benchmark years 1 and 2 to participate in the BASIC track. If those ACOs apply to renew their participation in a subsequent agreement period and have at least 5,000 assigned beneficiaries in all 3 BYs, they may be eligible to enter an agreement period under the ENHANCED track.

Additionally, we disagree with commenters that "these changes would discourage the formation

of new ACOs and penalize existing ACOs for changes outside their control, undermining the goal of the Shared Savings Program to expand access to coordinated, high quality care." Conversely, as described in the Regulatory Impact Analysis of the CY 2026 PFS proposed rule (90 FR 32816 and 32817), we estimate that this proposal is expected to marginally increase participation by ACOs that would otherwise been unable to satisfy the 5,000 assigned beneficiary minimum in BY1, BY2, or both. We believe this approach will increase participation by ACOs with smaller assigned beneficiary populations.

Comment: A commenter is concerned that if it wishes to join the Shared Savings Program and has fewer than 5,000 beneficiaries in BY1, BY2, or both, that it will not be allowed to participate under the BASIC track as CMS proposed, given its experience with performance-based risk Medicare ACO initiatives, which subsequently require its participation in the Shared Savings Program under the ENHANCED track, and thus will not be able to participate in the Shared Savings Program at all. This commenter recommended that CMS allow ACOs with fewer than 5,000 beneficiaries in BY1, BY2, or both, to participate in the ENHANCED track.

Response: We clarify for the commenter that ACOs experienced with performance-based risk Medicare ACO initiatives and that they have fewer than 5,000 beneficiaries in BY1, BY2, or both, may participate in Level E of the BASIC track per § 425.600(h)(2) and (3) (as amended by this final rule). Such organizations would not be prohibited from participation in the Shared Savings Program. Further, regarding the recommendation that CMS allow ACOs with fewer than 5,000 beneficiaries in BY1, BY2, or both, to participate in the ENHANCED track, we reiterate our earlier response in this section.

Comment: A few commenters, while supportive of this policy, recommended CMS consider reducing the 5,000-assigned beneficiary requirement in all benchmark years and performance years to encourage greater participation, similar to ACO REACH.

Response: We thank commenters for their feedback, and we point commenters to section III.F.4.b.(1)(a) of this final rule and reiterate that maintaining this 5,000-assigned beneficiary minimum for BY3 using the most recent data available prior to an ACO entering an agreement period maximizes the goals and benefit of the Shared Savings Program. Moreover, as discussed in the CY 2026 PFS proposed rule (90 FR 32664), section 1899(b)(2)(D) of the Act requires participating ACOs to include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned

to the ACO and that, at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it under section 1899(c) of the Act in order to be eligible to participate in the Shared Savings Program. ACO REACH, on the other hand, is a model tested by the CMS Innovation Center using CMS' authority under section 1115A of the Social Security Act and does not have this statutory requirement of a beneficiary minimum in any benchmark year. Further, there are fundamental differences between the Shared Savings Program benchmarking methodology compared to the ACO REACH benchmarking methodology that warrant this requirement for 5,000 assigned beneficiaries in BY3 for the Shared Savings Program. For example, ACO REACH Standard ACOs are required to have at least 3,000 beneficiaries that would have been aligned via claims-based alignment in at least one of the three base years.[406] Further, the Shared Savings Program uses ACO-based assignment whereas ACO REACH uses a TIN/NPI based alignment.

Comment: A couple of commenters suggested that CMS also consider a 6-month grace period to allow an ACO to be able to reach the 5,000-assigned beneficiary minimum. Similarly, another commenter suggested an extended assignment period for beneficiaries, allowing new ACO entrants more time to meet the threshold while acknowledging that they would assume financial risk during this extended ramp-up phase.

Response: We thank commenters for their suggestions. A 6-month grace period for retroactively increasing BY3 assignment is not feasible, as the ACO would be in the first performance year of its agreement period during that same 6-month window. CMS would not be able to calculate a reliable benchmark for ACOs to be reconciled against until the performance year on which they are assessed has nearly concluded. Further, we are unsure what the commenter means by suggesting an "extended ramp-up phase," but we interpret that the commenter means to refer to an extended assignment window similar to this 6-month grace period. We reiterate our response that this would not be feasible for the same reason.

Comment: A couple of commenters suggested CMS should still allow for prepaid shared savings for those low revenue ACOs that do not meet the minimum 5,000-beneficiary threshold.

Response: We clarify for commenters that these proposed policies do not impact the eligibility

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[406] Centers for Medicare & Medicaid Services. (2022, April). *ACO Realizing Equity, Access, and Community Health (REACH) Model: Frequently Asked Questions* (Version 1). https://www.cms.gov/priorities/innovation/media/document/aco-reach-genfaqs

requirements for prepaid shared savings, and that whether an ACO is a low revenue ACO or a high revenue ACO does not impact eligibility for prepaid shared savings.

Comment: A commenter supported many of the proposed changes to the Shared Savings Program but was concerned that "tightened beneficiary thresholds" will limit value-based care participation opportunities for smaller Shared Savings Program participants.

Response: We clarify for this commenter that the beneficiary minimum is not being tightened, but rather, we proposed to remove the minimum for BY1 and BY2. We reiterate that we estimate the flexibility provided by this policy will increase value-based care participation opportunities for smaller Shared Savings Program participants.

Comment: A commenter stated concern about this proposal for small ACOs, suggesting that "[p]articipation for small ACOs should be voluntary, as these organizations face higher financial and operational risks."

Response: CMS clarifies for the commenter that participation in the Shared Savings Program is voluntary, and nothing about our proposed changes affects the voluntariness of that participation.

After consideration of public comments, we are finalizing the policies discussed in this section as proposed. Specifically, we are finalizing revisions to § 425.110 as follows. At § 425.110(a), we are finalizing our revision to paragraph (2) by adding the introductory phrase, "For agreement periods beginning before January 1, 2027", to limit the timing of applicability of the provision.

We are finalizing the addition of a new paragraph (3) to § 425.110(a) specifying that for agreement periods beginning on or after January 1, 2027, we determine whether an ACO has 5,000 or more beneficiaries historically assigned to the ACO participants in each of the three benchmark years, as calculated using the assignment methodology set forth in subpart E of Part 425. We are also finalizing with minor modification for consistency with our existing regulation text at § 425.110(a)(2) the provision under new § 425.110(a)(3) that states, in the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries. Additionally, we are finalizing in § 425.110(a)(3)(i) through (ii) the following provisions in connection with our determination of whether an ACO has 5,000 or more assigned beneficiaries in its benchmark years.

- We will deem an ACO to have initially satisfied the requirement to have at least 5,000

assigned beneficiaries as specified at § 425.110(a)(1) if 5,000 or more beneficiaries are historically assigned to the ACO participants in the third benchmark year.

- If an ACO has fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, the ACO may only participate under the BASIC track in accordance with new § 425.600(h)(3) (as described in sections III.F.2. and III.F.4.b.(2)(b) of this final rule).

c. Calculating Shared Savings and Losses for ACOs that Fall Below 5,000 Assigned Beneficiaries

(1) Apply an Alternative Performance Payment Limit and Loss Recoupment Limit during Financial Reconciliation for ACOs that Fall Below 5,000 Assigned Beneficiaries in any Benchmark Year

(a) Background

Section 1899(d)(2) of the Act addresses how payments for shared savings are to be determined and states that the Secretary shall establish limits on the total amount of shared savings that may be paid to an ACO under that provision. Section 1899(i) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model(s) will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We have used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models.[407] Under the authority granted by sections 1899(d)(2) and 1899(i)(1) of the Act, over time we have adopted methods to determine and limit performance payments and loss recoupment. We refer readers to discussions in earlier rulemaking on establishing the performance payment limit and loss recoupment limit for Levels A through E of the BASIC track (83 FR 67842 through 67857) and the ENHANCED track, formerly named Track 3 (80 FR 32778 and 32779). The track- or level- specific caps are described in section III.F.4.b.(1)(b) of this final rule.

When we calculate the performance payment limit, which is the maximum amount of earned shared savings an ACO can receive in a performance year, in the determination of an ACO's shared savings, we first calculate an ACO's per capita updated benchmark expenditures for the performance year

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[407] See earlier rulemaking establishing two-sided models, including Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 and 32772), and the BASIC track (83 FR 67834 through 67841). We also used our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID-19 (see § 425.611(c)(3) and 85 FR 27577 through 27582), SAHS billing activity for CY 2023 (see § 425.670(c)(3) and 89 FR 79161), and SAHS billing activity, from ACO participants' Medicare FFS revenue used to determine the loss recoupment limit in the two-sided models of the BASIC track for CY 2024 and subsequent calendar years (see § 425.672(c)(3) and 89 FR 98199 and 98200).

and then multiply this value by the ACO's assigned beneficiary person years[408] for the performance year, which equals their total benchmark expenditures. We then calculate the performance payment limit as a percentage of total benchmark expenditures, with the applicable percentage dependent on the ACO's track/level of participation (either 10 percent for all levels of the BASIC track, or 20 percent for the ENHANCED track). An ACO's earned shared savings payment is capped at the ACO's performance payment limit amount. See §§ 425.600(a)(3)-(4), 425.605, and 425.610 and the discussion in section III.F.4.b.(1)(b) of this final rule.

When we calculate the benchmark-based loss recoupment limit, which is the maximum amount of losses an ACO can owe in a performance year, in the determination of an ACO's shared losses, we calculate an ACO's per capita benchmark expenditures and then multiply this value by the ACO's assigned beneficiary person years for the performance year, which equals their total benchmark expenditures. We then calculate the loss recoupment limit as a percentage of total benchmark expenditures, with the applicable percentage dependent on the ACO's track/level of participation as described at §§ 425.600(a)(3) through (4), 425.605, and 425.610 and in section III.F.4.b.(1)(b) of this final rule: either 1 percent for Level C, 2 percent for Level D, or 4 percent for Level E of the BASIC track, or 15 percent for the ENHANCED track.

With respect to ACOs participating in two-sided model levels of the BASIC track, the loss recoupment limit is a percentage of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO (revenue-based loss recoupment limit) not to exceed a percentage of the ACO's updated benchmark (benchmark-based loss recoupment limit). We calculate the revenue-based loss recoupment limit as a percentage of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO. If the amount of the ACO's revenue-based loss recoupment limit exceeds the amount of the benchmark-based loss recoupment limit, we apply the benchmark-based loss recoupment limit. Refer to § 425.605(d)(1)(iii)(D), (d)(1)(iv)(D), and (d)(1)(v)(D). The percentages of the revenue-based and benchmark-based loss recoupment limits vary based on the Level of the BASIC track, as described in section III.F.4.b.(1)(b) of this final rule, providing for increasing performance-based risk along the two-

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[408] Person years are the fraction of the year during which the beneficiary was enrolled in each Medicare enrollment type. To calculate person years: CMS sums the number of Shared Savings Program-eligible months for the beneficiary for each Medicare enrollment type; CMS then divides this number by 12 (the number of months in a calendar year).

sided model levels of the BASIC track's glide path: 2 percent of ACO participant revenue capped at 1 percent of updated benchmark under Level C; 4 percent of ACO participant revenue capped at 2 percent of updated benchmark under Level D; and 8 percent of ACO participant revenue capped at 4 percent of updated benchmark under Level E.

We detailed how CMS calculates the benchmark-based performance payment limits and loss recoupment limits in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications, (June 2025, Version #13), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-4* (see section 4.3 "Performance Year Financial Reconciliation Calculations" and section 3.3 "ACO Participants' Revenue").

(b) Revisions

As described in the CY 2026 PFS proposed rule (90 FR 32668 through 32671), for ACOs with fewer than 5,000 assigned beneficiaries in any benchmark year, we proposed an alternative limit to performance payments and loss recoupment applicable for these ACOs in agreement periods beginning on or after January 1, 2027. We proposed that this policy would apply during financial reconciliation for any performance year in an agreement period for which the ACO was assigned fewer than 5,000 beneficiaries in any benchmark year. These alternative caps would help to safeguard ACOs and the Medicare Trust Funds by imposing stricter limits on performance payments and loss recoupment for ACOs with fewer than 5,000 assigned beneficiaries in any of their benchmark years at the time of financial reconciliation compared to the limits on performance payments and loss recoupment under the current methodology. The proposed timing of applicability for this policy would be consistent with the timing of applicability for our proposed approach to allow participation by ACOs with 5,000 assigned beneficiaries in BY3, and fewer than 5,000 assigned beneficiaries in BY1, BY2, or both (90 FR 32665 and 32666).

We explained that there are a number of possible circumstances that could cause an ACO's assigned beneficiary population in the benchmark years to fall below 5,000 assigned beneficiaries. Under our proposal, for agreements periods beginning on or after January 1, 2027, we would allow for

participation by ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both (90 FR 32666 and 32667). Additionally, regardless of the number of assigned beneficiaries an ACO has at the time of program entry, the ACO's assigned population for its benchmark years may be adjusted during the course of its 5-year agreement period. For example, as described in § 425.652(a)(9), an ACO may receive an adjusted historical benchmark because of changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection at § 425.226(a)(1), or changes to the beneficiary assignment methodology specified in 42 CFR part 425 subpart E, among other changes. Participant list changes occurring within an agreement period, for example, could result in an ACO falling below 5,000 historically assigned beneficiaries in any benchmark year, including BY3, for the purpose of the performance year financial reconciliation.

As we described in the CY 2026 PFS proposed rule (90 FR 32668), under this proposed approach, we would use an alternative calculation for the benchmark-based[409] performance payment limits and loss recoupment limits, in which we would compute an ACO's total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures and the ACO's assigned beneficiary person years from the benchmark year with the lowest number of assigned beneficiaries. We noted that we would only use this alternative calculation if an ACO has fewer than 5,000 historically assigned beneficiaries in a benchmark year; otherwise, we would use our current performance payment limit calculation that uses the ACO's assigned beneficiary person years from benchmark year 3 (BY3). More specifically, we would multiply the person years for assigned beneficiaries for the benchmark year with the lowest number of assigned beneficiaries by the ACO's per capita benchmark expressed as a single value to get an ACO's alternative total benchmark expenditures. We would calculate the product of the track/level specific percentage used to calculate the benchmark-based performance payment limit, or loss recoupment limit, and the ACO's alternative amount of total benchmark expenditures. We would also continue to compute a benchmark-based performance payment limit and loss recoupment limit for the ACO, specified for the ACO's track/level of participation.

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[409] This proposal would not change the calculation of the revenue-based loss sharing limit.

We proposed comparing the alternative benchmark-based performance payment limit or loss recoupment limit (calculated using assigned beneficiary person years from the benchmark year with the lowest number of assigned beneficiaries) with the benchmark-based performance payment limit or loss recoupment limit calculated with assigned beneficiary person years for the performance year. We would apply the lesser of these two aforementioned amounts (in absolute value) in determining the final performance payment limit or loss recoupment limit. This approach would ensure that no ACO would receive a larger cap with the alternative performance payment limit or loss recoupment limit than it would receive under the current methodology.

We proposed to specify the proposed approach in amendments to the Shared Savings Program regulations at new § 425.605(i) (BASIC track) and new § 425.610(l) (ENHANCED track).

At new § 425.605(i), we proposed to include provisions to codify the current approach to calculating the performance payment limit under new paragraph (i)(1)(i), and the loss recoupment limit under new paragraph (i)(2)(i). We proposed to specify under new paragraphs (i)(1)(ii) and (i)(2)(ii) of § 425.605 provisions for how CMS determines whether to apply an alternative performance payment limit or loss recoupment limit (respectively), if an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or BY3, in conducting financial reconciliation for each performance year, for agreement periods beginning on or after January 1, 2027. At this new § 425.610(l)(1) to (2), we proposed to include provisions to codify the current approach to calculating the performance payment limit, and the loss recoupment limit. We proposed to specify under new paragraph (l)(3) of § 425.610 provisions for how CMS determines whether to apply an alternative performance payment limit or loss recoupment limit if an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or BY3, in conducting financial reconciliation for each performance year, for agreement periods beginning on or after January 1, 2027.

The proposed policies to potentially reduce the limit on performance payments and loss recoupment limit when an ACO falls below 5,000 assigned beneficiaries in any benchmark year would safeguard the overall financial integrity of the Shared Savings Program, including the Trust Funds, and protect ACOs. The proposed policies would potentially limit shared savings and shared losses in the event that a historical benchmark may be less reliable due to a smaller (fewer than 5,000) assigned beneficiary population size in any benchmark year. We also explained that, as an ACO's assigned beneficiary

population decreases, variability in the population's expenditures increases. The reduction in the size of the ACO's assigned beneficiary population in benchmark years could result in variability in benchmark calculations, which could cause shared savings payments made to the ACO or shared losses owed to be based on normal expenditure fluctuations, rather than reflect actual program performance. We explained our expectation that these alternative caps would apply to ACOs rarely; when applied, we expect these alternative caps to have limited reductions to an ACO's shared savings or shared losses payments but to provide adequate protection and risk mitigation in outlier cases. In an analysis of the performance year reconciliation data for performance years 2020-2023, CMS found that on average, only 2 percent of ACOs at the time of financial reconciliation have at least one benchmark year below 5,000 assigned beneficiaries.

Tables B-G3 and B-G4 provide examples of the alternative performance payment limit and alternative loss recoupment limit calculations that would apply for an ACO with fewer than 5,000 assigned beneficiaries in at least one benchmark year under this proposal.

TABLE B-G3: EXAMPLE ALTERNATIVE PERFORMANCE PAYMENT LIMIT CALCULATION

Determine which BY corresponds with the lowest number of assigned beneficiaries as determined at the time of financial reconciliation.	Number of assigned beneficiaries for each BY, determined at the time of financial reconciliation. BY1: 4,300 BY2: 3,900 BY3: 5,500 BY with lowest number of assigned beneficiaries: **BY2**
Determine number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries, determined at the time of financial reconciliation.	Number of assigned beneficiary person years for each BY, determined at the time of financial reconciliation. BY1: 3,550 BY2: 3,250 BY3: 5,050 Number of assigned beneficiary person years for BY2: **3,250**
Calculate alternative total benchmark expenditures based on number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries.	Per capita benchmark expenditures[1]: $13,000 Alternative total benchmark expenditures: $13,000 * 3,250 = **$42,250,000**
Calculate alternative performance payment limit based on Track-specific percentage.	ACO Track: BASIC Track Level E Alternative performance payment limit: 10% * $42,250,000 = **$4,225,000**
Compare alternative performance payment limit to existing performance payment limit and apply the lesser value.	Existing performance payment limit: ($13,000 per capita benchmark expenditures * 5,050 PY person years) *10% = **$6,565,000** Final performance payment limit: **$4,225,000**

Notes: [1] Updated Per Capita Benchmark Expenditures expressed as a single value ($).

TABLE B-G4: EXAMPLE ALTERNATIVE LOSS RECOUPMENT LIMIT CALCULATION

Determine which BY corresponds with the lowest number of assigned beneficiaries as determined at the time of financial reconciliation.	Number of assigned beneficiaries for each BY, determined at the time of financial reconciliation. BY1: 4,300 BY2: 3,900 BY3: 5,500 BY with lowest number of assigned beneficiaries: **BY2**
Determine number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries, determined at the time of financial reconciliation.	Number of assigned beneficiary person years for each BY, determined at the time of financial reconciliation. BY1: 3,550 BY2: 3,250 BY3: 5,050 Number of assigned beneficiary person years for BY2: **3,250**
Calculate alternative total benchmark expenditures based on number of assigned beneficiary person years for the BY with the lowest number of assigned beneficiaries.	Per capita benchmark expenditures[1]: **$13,000** Alternative total benchmark expenditures: $13,000 * 3,250 = **$42,250,000**
Calculate alternative loss recoupment limit based on Track-specific percentage.	ACO Track[2]: BASIC Track Level E 8% of ACO Participant Total Medicare Parts A and B FFS Revenue: **$2,750,000** 4% of Alternative total benchmark expenditures: **$1,690,000** Alternative loss recoupment limit: -4% * $42,250,000 = **-$1,690,000**
Compare alternative loss recoupment limit to existing loss recoupment limit and apply the lesser absolute value.	Existing loss recoupment limit [3]: ($13,000 per capita benchmark expenditures * 5,050 PY person years) *-4% = -$**2,626,000** Final loss recoupment limit: **-$1,690,000**

Notes: [1] Updated Per Capita Benchmark Expenditures expressed as a single value ($).
[2] For BASIC Track Level E, if 8 percent of total Medicare Parts A and B FFS Revenue for ACO Participants is greater than 4 percent of Total Benchmark Expenditures, then the loss recoupment limit is equal to -4 percent of Total Benchmark Expenditures.
[3] In this case, the ACO's revenue-based loss sharing limit exceeds the benchmark-based loss sharing limit; therefore, the ACO's loss sharing limit is based on total benchmark expenditures.

In the CY 2026 PFS proposed rule (90 FR 32667), we explained that we have used our authority under section 1899(i)(3) of the Act to establish the two-sided payment models of the BASIC track and ENHANCED track, including the current approach to calculating the loss recoupment limits (based on the ACO's assigned beneficiary person years for the performance year). Therefore, we proposed to continue to use our authority under section 1899(i)(3) of the Act to implement our proposal to apply the lower of a loss recoupment limit calculated based on performance year assigned beneficiary person years, or an alternative loss recoupment limit calculated based on the ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries, in conducting financial reconciliation for a performance year in agreement periods beginning on or after January 1, 2027.To implement this alternative payment model under the Secretary's authority under section 1899(i) of the Act, we must determine that it would improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. As discussed further in the Regulatory

Impact Analysis of the CY 2026 PFS proposed rule (90 FR 32814 through 32818), we projected that the proposed change to apply an alternative loss recoupment limit for ACOs with fewer than 5,000 assigned beneficiaries in any BY, in combination with other proposed changes to the statutory payment model in the CY 2026 PFS proposed rule, as well as current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program, and would not be expected to increase program expenditures relative to those of the statutory payment model.

As described in the Regulatory Impact Analysis for the CY 2026 PFS proposed rule (90 FR 32817), by potentially reducing shared savings payments to outliers with sharp growth in beneficiary assignment during the agreement period despite benchmark year beneficiary assignments dropping below the current 5,000-beneficiary minimum, the program may see additional net savings to the Medicare Trust Funds as compared to the current policy. Meanwhile, the alternative loss recoupment limit is not expected to materially reduce shared losses collected by the program as only a few ACOs have shared losses, and those losses rarely approach the regular benchmark-based loss recoupment limit. Also, the alternative loss recoupment limit would potentially marginally increase participation in the Shared Savings Program by providing certain ACOs greater assurance that they would be protected from elevated exposure to unusually large shared loss liabilities in rare situations where their assignment counts could decrease well below 5,000 beneficiaries. Attracting additional ACOs to the Shared Savings Program increases the number of providers and suppliers who are working together to coordinate care for beneficiaries, providing quality care at lower cost.

We sought comments on the proposals to apply an alternative performance payment limit and loss recoupment limit during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries in any benchmark year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposals to calculate an alternate performance payment limit and loss recoupment limit for ACOs with fewer than 5,000 assigned beneficiaries in the benchmark years. Some commenters stated support specifically in consideration of the fact that smaller

ACOs may have greater variance in savings and losses compared to larger ACOs. A couple of commenters indicated support of this policy specifically because it may discourage "gaming by ACOs." Some commenters stated appreciation of these policies specifically as an opportunity for new, renewing or re-entering ACOs that have successfully participated in the program and were impacted by the previous policies to continue their program participation without any further disruption. A commenter specifically supported these changes and policies that will continue to support smaller ACOs and practices, and those in rural and underserved communities, to participate and succeed in the Shared Savings Program and other value-based payment models.

Response: We thank commenters for their support.

Comment: A commenter had concerns about having shared savings and losses "capped throughout the agreement period". This commenter stated that these restrictions may discourage participation from ACOs that would otherwise qualify under the "revised threshold." The commenter indicated that capping shared savings reduces the potential return on investment, which may lead some ACOs — particularly those without large beneficiary pools or financial reserves — to forgo participation altogether, and that this would be counterproductive to the agency's stated goal of broadening Shared Savings Program participation. This commenter urges CMS to reconsider the across-the-board cap on shared savings and losses.

Response: We do not share the commenter's concerns about potential adverse effects on Shared Savings Program participation under the proposed approach, and believe the comment indicates a potential misunderstanding of the proposal. First, we remind the commenter that this proposed approach would not permanently cap an ACO's shared savings and losses "throughout the agreement period", but rather determines whether to apply the existing or alternative caps each performance year of the agreement period. If, for example, an ACO adds ACO participants to its ACO participant list and those changes result in the ACO meeting or exceeding 5,000 assigned beneficiaries for each of its benchmark years, the alternative caps would not apply.

As described in the Regulatory Impact Analysis of the CY 2026 PFS proposed rule (90 FR 32816 and 32817) and reiterated in the related analysis in section VI of this final rule, we anticipate the changes we are finalizing to allow for additional flexibility in eligibility requirements, in combination with the

alternative caps on shared savings or shared losses, will marginally increase Shared Savings Program participation over the 10 year projection window from 2026 to 2035. Although a number of possible circumstances could cause an ACO's assigned beneficiary population in the benchmark years to fall below 5,000 assigned beneficiaries during its agreement period, the proposal to apply alternative performance payment and loss recoupment limits for ACOs with less than 5,000 assigned beneficiaries in any BY is one of several safeguards we believe is necessary to address risk to the program that result from the proposed changes to the eligibility requirements to allow for participation by ACOs that have fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, which we are finalizing with this final rule (see section III.F.4.b.(2)(a) of this final rule). As discussed elsewhere in this final rule, the policy to reduce the limits on performance payments and loss recoupment when an ACO falls below 5,000 assigned beneficiaries in any benchmark year would safeguard the overall financial integrity of the Shared Savings Program, including the Medicare Trust Funds, and also protect ACOs. More specifically, application of the alternative performance payment limit would potentially reduce shared savings payments to outliers with sharp growth in beneficiary assignment during the agreement period despite benchmark year beneficiary assignments dropping below the current 5,000-beneficiary minimum, and as a result the program may see additional net savings to the Medicare Trust Funds as compared to the current policy. The alternative loss recoupment limit is not expected to materially reduce shared losses collected by the program, as based on recent experience, only a few ACOs have shared losses, and those losses rarely approach the regular benchmark-based loss recoupment limit.

In an analysis of performance year reconciliation data for performance years 2020-2024,[410] we have found that on average, only 2 percent of ACOs at the time of financial reconciliation had at least one benchmark year below 5,000 assigned beneficiaries where the alternative cap would apply. Of these ACOs that would have had the alternative cap applied, none reached or exceeded the alternative cap, meaning none of these ACOs would have had their shared savings or losses reduced as compared to the shared savings or losses they actually experienced. Specifically, the shared savings earned by these ACOs would have to more than double on average to reach the alternative cap, which further supports our belief

[410] Related analysis of reconciliation data for PY 2020 through 2023 was described in the CY 2026 PFS proposed rule (90 FR 32669). Since the issuance of the CY 2026 PFS proposed rule, we completed financial reconciliation for PY 2024.

that the alternative cap will not result in reduced return on investment that would deter Shared Savings Program participation. While none of these ACOs would have reached or exceeded the cap in this simulation, it is important to recognize this analysis relied on ACOs that were required to have at least 5,000 beneficiaries in the benchmark years at the time of program entry. By no longer requiring ACOs to enter the program with at least 5,000 assigned beneficiaries in BY1 and BY2 the program will at least in theory be open to ACOs with very low assignment in the first two benchmark years, and thus the alternative cap will act as a safeguard against the earned performance payment or losses owed based on random variation for such outlier ACOs even if the actual number of ACOs that reach or exceed the cap remains limited in practice.

After consideration of public comments, we are finalizing the application of an alternative performance payment limit and loss recoupment limit during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries in any benchmark year as proposed. We are finalizing proposed revisions to the Shared Savings Program regulations at new § 425.605(i) (BASIC track) and new § 425.610(l) (ENHANCED track). At new § 425.605(i), we are finalizing our proposal to codify the existing approach to calculating the performance payment limit under new paragraph (i)(1)(i), and the loss recoupment limit under new paragraph (i)(2)(i). We are finalizing in new paragraphs (i)(1)(ii) and (i)(2)(ii) of § 425.605 provisions for how CMS determines whether to apply an alternative performance payment limit or loss recoupment limit (respectively), if an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or BY3, in conducting financial reconciliation for each performance year, for agreement periods beginning on or after January 1, 2027. At new § 425.610(l)(1) to (2), we are finalizing as proposed provisions to codify the existing approach to calculating the performance payment limit, and the loss recoupment limit. We are finalizing, with a minor modification for consistency and clarity, our proposal to specify under new paragraph (l)(3) of § 425.610 provisions for how CMS determines whether to apply an alternative performance payment limit or loss recoupment limit if an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or BY3, in conducting financial reconciliation for each performance year, for agreement periods beginning on or after January 1, 2027. Specifically, we are finalizing a modification to the text of paragraph (l)(3)(iii) to remove the term “equal” such that the finalized regulation text at § 425.610(l)(3)(iii) will read as follows, “The performance payment limit or

loss recoupment limit is set to the lesser of the amount calculated under paragraph (l)(2)(ii) of this section or the alternative amount calculated under paragraph (l)(3)(ii) of this section."

(2) Exclude ACOs that Fall Below 5,000 Assigned Beneficiaries in any BY from Policies Providing Certain Low Revenue ACOs Participating in the BASIC Track Increased Opportunities to Share in Savings

(a) Background

With the CY 2023 PFS final rule (87 FR 69946 through 69952), we finalized an approach, under our authority of section 1899(i)(3) of the Act,[411] to expand the eligibility criteria to qualify for shared savings payments to enable certain low revenue ACOs participating in the BASIC track to share in savings even if the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act. In accordance with § 425.605(h), ACOs participating in the BASIC track that do not meet the MSR requirement, but that do meet the quality performance standard or the alternative quality performance standard at § 425.512 and otherwise maintain eligibility to participate in the Shared Savings Program, qualify for a shared savings payment if all the following criteria are met:

- The ACO has average per capita Medicare Parts A and B FFS expenditures for the performance year below the updated benchmark (§ 425.605(h)(1)(i)).
- The ACO is a low revenue ACO as defined at § 425.20 as determined at the time of financial reconciliation for the performance year (§ 425.605(h)(1)(ii)).
- The ACO has at least 5,000 assigned beneficiaries for the performance year at the time of financial reconciliation for the performance year (§ 425.605(h)(1)(iii)).
- The ACO is participating in an agreement period beginning on January 1, 2024, or in subsequent years (§ 425.605(h)(1)(iv)).

Section 425.605(h)(2) specifies the sharing rate applied for ACOs that meet the aforementioned criteria, which is one-half the applicable percentage described at § 425.605(d). As we explained in the CY 2023 PFS final rule (87 FR 69948 and 69949), under this approach, an eligible ACO that does not meet the MSR but meets the quality performance standard required to share in savings at the maximum sharing rate receives half of the maximum sharing rate for their level of participation (20 percent instead of 40

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[411] See discussion on use of our authority under section 1899(i)(3) of the Act, at 87 FR 69950.

percent under Levels A and B, and 25 percent instead of 50 percent under Levels C, D, and E). Where an eligible ACO does not meet the MSR or the quality performance standard required to share in savings at the maximum sharing rate but meets the alternative quality performance standard, the sharing rate is further adjusted according to a sliding scale approach for determining shared savings.

(b) Revisions

In the CY 2026 PFS proposed rule (90 FR 32671), we proposed to exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to benefit from the policies at § 425.605(h) that provide certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings**.** As we have explained in prior rulemaking (83 FR 67923 through 67926) and reiterated in the CY 2026 proposed rule (90 FR 32670), the MSR/MLR protects against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than actual program performance. ACOs with assigned beneficiary populations below 5,000 raise concerns that any shared savings payments made to the ACO would not reward true cost savings but instead would pay for normal expenditure fluctuations. To protect against issuing shared savings payments to certain low revenue ACOs participating in the BASIC track related to normal or random variation in expenditures, we proposed revising § 425.605(h) to include an additional criterion that ACOs must have at least 5,000 assigned beneficiaries in all three benchmark years at the time of financial reconciliation for a performance year to qualify for a shared savings payment at § 425.605(h). Specifically, we proposed to amend § 425.605(h)(1) by adding new paragraph (v) that specifies: "For agreement periods beginning on or after January 1, 2027, the ACO has at least 5,000 assigned beneficiaries in each of the ACO's benchmark years." The proposed timing of applicability for this policy would be consistent with the timing of applicability for our proposed approach to allow participation by ACOs with 5,000 assigned beneficiaries in BY3, and fewer than 5,000 assigned beneficiaries in BY1, BY2, or both.

We sought comments on the proposal to exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to benefit from policies at § 425.605(h) providing certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed their support for the proposal to exclude ACOs with fewer than 5,000 assigned beneficiaries in the benchmark years from additional opportunities for low revenue ACOs to share in savings because this policy overall may increase participation by additional new, renewing, or re-entering ACOs.

Response: We thank commenters for their support.

Comment: Many commenters had concerns about the proposal to exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to leverage existing policies that provide certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings, and urged CMS to reconsider the proposal.

Specifically, commenters stated if 5,000 assigned beneficiaries in BY3 is permissible for participation in the Shared Savings Program, it is unclear why it is necessary for these low revenue ACOs to have at least 5,000 assigned beneficiaries in all three benchmark years to receive these opportunities for shared savings. Furthermore, commenters indicated that current policies still require these ACOs to have at least 5,000 assigned beneficiaries for the performance year to be eligible for the shared savings opportunity. As a result, commenters stated this proposed change denies certain low revenue ACOs that have been accepted into the Shared Savings Program from receiving the same benefits as "similarly situated ACOs without a reasonable basis for doing so."

A commenter expressed concerns that removing access to an existing flexibility for this group undermines the value of the proposed eligibility change. This commenter requested that CMS to preserve the current opportunities for low revenue, BASIC track ACOs regardless of the benchmark year's beneficiary counts.

Response: We decline to adopt commenters' suggestions to forgo finalization of our proposal to exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to benefit from the policies at § 425.605(h) that provide certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings. As commenters point out, the current policy requires that the ACO have at least 5,000 assigned beneficiaries for the performance year at the

time of financial reconciliation for the performance year (§ 425.605(h)(1)(iii)). We agree that this existing requirement provides a certain degree of protection against the heightened risk – absent an MSR – that any savings are the result of random variation (see 87 FR 69949; see also 90 FR 32670 and 32671). However, this existing policy leaves the Trust Funds vulnerable to paying ACOs shared savings that may reflect normal or random variation in expenditures rather than true cost savings, when the ACO's historical benchmark is calculated based on smaller populations, and specifically less than 5,000 assigned beneficiaries in one or more BYs.

Our current policy under § 425.110(a), requiring ACOs to have at least 5,000 assigned beneficiaries in each benchmark year to enter an agreement period under the Shared Savings Program, helps ensure the financial integrity of benchmark calculations for ACOs. Even so, under our current policy, an ACO may continue participating in the Shared Savings Program with fewer than 5,000 assigned beneficiaries in one or more benchmark year. As a result, an ACO with fewer than 5,000 assigned beneficiaries in one or more benchmark year may be eligible for the expanded opportunities for shared savings, so long as the criteria under § 425.605(h) are met. As described elsewhere in this final rule, we performed analysis of performance year reconciliation data for PYs 2020 through 2024, finding that, on average, only 2 percent of ACOs at the time of financial reconciliation had at least one benchmark year with fewer than 5,000 assigned beneficiaries. Continuing this analysis, none of the ACOs identified with fewer than 5,000 assigned beneficiaries in a benchmark year would have otherwise met the criteria for additional opportunities for low revenue ACOs to share in savings if the criteria under § 425.605(h) had been applied to determining PY 2020 through 2023 financial reconciliation results. The policy for increased shared savings opportunities under § 425.605(h) applies to eligible ACOs participating in agreement periods beginning on January 1, 2024, or in subsequent years. Since the issuance of the CY 2026 PFS proposed rule, we completed financial reconciliation for PY 2024. Based on PY 2024 financial reconciliation results, 13 low revenue ACOs participating in the BASIC track for an agreement period beginning on January 1, 2024 were eligible to share in savings under the existing

requirements of § 425.605(h), of which 1 ACO had fewer than 5,000 assigned beneficiaries in one benchmark year.[412]

Under the proposed approach, which we are finalizing with this final rule, where we allow for ACOs to enter agreement periods with fewer than 5,000 assigned beneficiaries in BY1, BY2 or both, there is a greater possibility for ACOs to enter and remain in the Shared Savings Program with relatively smaller assigned beneficiary populations used to establish their historical benchmarks compared to our current eligibility policies. Therefore, we have heightened concerns that the Shared Savings Program will be more vulnerable to making shared savings payments to ACOs that would not reward true cost savings but instead would pay for normal or random expenditure fluctuations when smaller populations of assigned beneficiaries are used to establish the ACO's historical benchmark as a result of the ACO having fewer than 5,000 assigned beneficiaries in a benchmark year. This concern is further increased under the policy at § 425.605(h), under which certain low revenue, BASIC track ACOs may qualify for a shared savings payment when they have not met the MSR requirement.

We believe it is timely and appropriate to address the aforementioned concerns. Therefore, we are finalizing our proposal to amend § 425.605(h)(1) to include an additional criterion, applicable for agreement periods beginning on or after January 1, 2027, under which we will require an ACO to have at least 5,000 assigned beneficiaries in each of its BYs to be eligible for the increased opportunities to share in savings, under the policy established at § 425.605(h).

We acknowledge that, under this final policy, there could be a difference in the eligibility of ACOs for the increased opportunities to share savings, depending on the ACO's agreement period start date in the Shared Savings Program. ACOs participating in agreement periods beginning on January 1, 2024, 2025, or 2026 may be eligible for the increased opportunities to share in savings under § 425.605(h), for any performance year of their 5-year agreement period, while having fewer than 5,000 assigned beneficiaries in one or more benchmark year. In contrast, the additional criterion we are finalizing with this final rule would exclude ACOs participating in agreement periods beginning on or after January 1, 2027 from increased opportunities to share in savings under § 425.605(h) if they have

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[412] See Data.CMS.gov, Medicare Shared Savings Program, Performance Year Financial and Quality Results Public Use File, PY 2024, available at https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results.

fewer than 5,000 assigned beneficiaries in any benchmark year. We note that this approach is consistent with our longstanding practice of applying changes to the Shared Savings Program's financial methodology on an agreement period basis. Further, we would consistently apply the relevant policies, program-wide to ACOs, based on their agreement period start date.

After consideration of public comments, we are finalizing as proposed to amend § 425.605(h)(1) by adding new paragraph (v) that specifies: "For agreement periods beginning on or after January 1, 2027, the ACO has at least 5,000 assigned beneficiaries in each of the ACO's benchmark years." With this final policy, for agreement periods beginning on or after January 1, 2027, we will exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to benefit from policies at § 425.605(h) providing certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings.

5. Revisions to the Definition of Primary Care Services used in Shared Savings Program Beneficiary Assignment

a. Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), for performance years beginning on or after January 1, 2019. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212

and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825; 88 FR 79163 through 79174; 89 FR 98087 through 98101) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program. For the performance year beginning on January 1, 2025, and subsequent performance years, we defined primary care services for purposes of assigning beneficiaries to ACOs under § 425.402 at § 425.400(c)(1)(ix).

b. Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently used for payment under the PFS or that we proposed to use for payment under the PFS starting in CY 2026, we have determined it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes for the performance year starting on January 1, 2026, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

In the CY 2026 PFS proposed rule (90 FR 32671 through 32673), we proposed to specify a revised definition of primary care services used for assignment for the performance year starting on January 1, 2026, and subsequent performance years in a new provision of the Shared Savings Program at § 425.400(c)(1)(x) to include the list of HCPCS and CPT codes specified at § 425.400(c)(1)(ix), the addition of Enhanced Care Model Management Services (HCPCS codes (GPCM1, GPCM2, and GPCM3), and the deletion of Social Determinants of Health Risk Assessment Services (HCPCS code G0136), if finalized under Medicare FFS payment policy.

We proposed to use the new provision at § 425.400(c)(1)(x) for determining beneficiary assignment for the performance year starting on January 1, 2026, and in subsequent performance years.

The following provides additional information about the CPT and HCPCS codes that we proposed adding to the definition of primary care services used for purposes of beneficiary assignment:

Enhanced Care Model Management Services (HCPCS Codes GPCM1, GPCM2, and GPCM3): In the CY 2026 PFS proposed rule (90 FR 32496 through 32502), we proposed three new add-on HCPCS codes to allow for payment under the PFS when BHI or CoCM are furnished in conjunction with APCM

services for practitioners who meet the requirements to furnish both services. Specifically, we proposed to allow for payment of the following codes, discussed in more detail below, under the PFS: GPCM1, an add-on code that mirrors 99492 (CoCM initial month), GPCM2, an add-on code that mirrors 99493 (subsequent months) for CoCM services delivered to patients also receiving APCM services, and GPCM3, an add-on code for general behavioral health integration services that mirrors CPT code 99484 (20 minutes or more of BHI services) for BHI services delivered to patients also receiving APCM services.

● HCPCS code GPCM1 (*Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan, if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately and in addition to the Advanced Primary Care Management code)*).

● HCPCS code GPCM2 (*Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-*

based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment. (list separately and in addition to Advanced Primary Care Management code)).

● HCPCS code GPCM3 (*Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team (list separately and in addition to Advanced Primary Care Management code)*).

All of these codes were proposed as optional add-on codes for APCM services that would facilitate providing complementary BHI services by removing the time-based requirements and reducing documentation requirements of the existing BHI and CoCM CPT codes. In the proposed rule, we stated that we believe removing the time-based requirements and reducing the documentation requirements may make primary care practitioners more likely to offer BHI and CoCM services, which would improve access to BHI and CoCM for primary care patients and access to primary care for BHI and CoCM patients.

These new HCPCS codes are designed to allow for the payment of services that, when reported as standalone services, are currently included in the definition of primary care services used for purposes of assignment when furnished in conjunction with APCM services: BHI (CPT codes 99484, 99492, 99493 and 99494), CoCM (HCPCS code G2214), and APCM (HCPCS codes G0556, G0557, and G0558) (refer to 82 FR 53212 through 53213, 85 FR 84750 through 84755, and 89 FR 98087 through 98097, respectively).

The new HCPCS codes are also similar to CPT codes 99354 and 99355 (83 FR 59965 through 59968), which likewise are included in the definition of primary care services used for purposes of

assignment. Including these new HCPCS codes for BHI and CoCM APCM add-on services into the definition of primary care services used for purposes of assignment would increase the accuracy of assignment based on the provision of primary care by ensuring that all expenditures for BHI and CoCM are used to determine beneficiary assignment.

The following provides additional information about the CPT and HCPCS codes that we proposed to remove from the definition of primary care services used for purposes of beneficiary assignment:

HCPCS code G0136 (Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5-15 minutes): In the CY 2026 PFS proposed rule (90 FR 32510), we proposed to delete HCPCS code G0136 as we believed that the resource costs described by HCPCS code G0136 were already accounted for in existing codes, including but not limited to evaluation and management visits. Accordingly, we proposed not to include this HCPCS code in the definition of primary care services used for purposes of assignment, beginning January 1, 2026, and in subsequent years, if the deletion is finalized.

As part of this revised definition of primary care services used for assigning beneficiaries at § 425.402, we proposed to incorporate a provision at § 425.400(c)(1)(x)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified at § 425.400(c)(1)(x)(A) or a HCPCS code specified at § 425.400(c)(1)(x)(B), when the assignment window or expanded window for assignment (as defined at § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under Medicare FFS.

We sought comments on these proposed changes to the definition of primary care services used for assigning beneficiaries at § 425.400(c)(1)(x) to Shared Savings Program ACOs for the performance year starting on January 1, 2026, and subsequent performance years. We also sought comments on any other existing or new HCPCS or CPT codes that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposed revisions to the definition of primary care services used for purposes of assignment to include complementary behavioral health integration or psychiatric Collaborative Care Model services, noting that adding these codes would capture more of the services rendered by primary care physicians to beneficiaries and increase participation in the Shared Savings Program. Commenters stated that these additional service codes support the delivery of comprehensive, coordinated, whole-person care and are reflective of other primary care services CMS has used to assign beneficiaries to ACOs.

Response: We agree with commenters that the proposed revisions to include complementary behavioral health integration and psychiatric Collaborative Care Model services to the definition of primary care services will capture more of the primary care services rendered by primary care providers as a part of whole-person care and might increase participation in the Shared Savings Program by providers who wish to assume accountability for the care of beneficiaries with behavioral health needs. We also agree that the use of these additional service codes for purposes of assignment, if it leads to the inclusion of more primary care providers who are care coordinating and addressing their patients' behavioral health needs, would support the delivery of comprehensive, coordinated, whole-person care.

Comment: A commenter stated that add-on codes should not be used for beneficiary assignment, explaining that using the base procedure is sufficient and that add-on codes associated with a base procedure should not be included in the definition of primary care services for beneficiary assignment for the Shared Savings Program. The commenter described their concern about a situation where one provider who renders a primary service with three add-on services would receive priority over a different provider from whom the beneficiary received three separate primary services.

Response: The commenter may not have fully understood how claims-based beneficiary assignment occurs in the Shared Savings Program. In performing claims-based assignment, CMS determines whether allowed charges for a beneficiary's primary care services in an ACO, are greater than allowed charges for the beneficiary's primary care services in any other ACO, or other individual practitioners, or groups of practitioners identified by Medicare-enrolled billing TINs or CCNs that are not participating in the Shared Savings Program, otherwise known as plurality of primary care services. Since these are add-on services, they would be billed and furnished by the same provider that bills and furnished

the base service.

As a “pre-step” in the claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations specified in § 425.402(c). Under claims-based assignment, CMS assigns beneficiaries to ACOs through one of three steps. Under Step 1, CMS assigns a beneficiary to a Shared Savings Program ACO when the beneficiary receives more primary care services (measured by Medicare-allowed charges) furnished by primary care physicians, nurse practitioners, physician assistants and clinical nurse specialists in the participating ACO than from the same type of providers at any other Shared Savings Program ACO, non-ACO CCN, or non-ACO individual or group TIN. Step 2 only applies to assignable beneficiaries who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO and were therefore not assigned in assignment Step 1. CMS assigns a beneficiary to a Shared Savings Program ACO in this step when the beneficiary receives more primary care services (measured by Medicare-allowed charges) furnished by physicians who are ACO professionals with specialty designations as specified in § 425.402(c) in the participating ACO than from the same type of providers at any other Shared Savings Program ACO, non-ACO CCN, or non-ACO individual or group TIN. In step three, CMS utilizes an expanded window for assignment to identify additional beneficiaries for assignment among Medicare FFS beneficiaries who were not identified under the existing pre-step. The expanded window for assignment is a 24-month period that includes the applicable 12-month assignment window and the preceding 12 months.

We expect that the assignment algorithm will ensure appropriate assignment to an ACO when using these add-on HCPCS codes, and we will monitor the billing and utilization of these codes to ensure that their inclusion in the definition of primary care services used for beneficiary assignment is appropriate, including by monitoring and evaluating place of service and provider specialty associated with billed claims for these add-on HCPCS codes. If monitoring shows that the inclusion of these services in the definition of primary care services used for beneficiary assignment is not appropriate, we will address that concern in future notice and comment rulemaking.

Since these HCPCS codes represent new add-on services to HCPCS codes that are already included in the definition of primary care services used for purposes of assignment, we continue to believe that these new procedure codes should be included in the definition of primary care services used for purposes of assignment consistent with our intent to encompass primary care and wellness services in the definition of primary care services used for purposes of beneficiary assignment.

Comment: Multiple commenters supported our proposal to remove HCPCS code G0136 from the definition of primary care services if CMS finalizes its proposal to delete HCPCS code G0136.

Response: We appreciate commenters' support for our proposal. However, we have decided not to finalize our proposal to delete HCPCS code G0136 from the HCPCS code set. As described in section II.I of this final rule, we are instead revising the code descriptor to the following text: *G0136 – [Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5-15 minutes, not more often than every 6 months].* Since HCPCS code G0136 is not being deleted and it remains a payable service under the PFS, we are not finalizing our proposal to remove the code from the definition of primary care services for purposes of assignment. We continue to believe that G0136 should remain a part of the definition of primary care services used for purposes of assignment because, as described in the CY 2024 PFS Final Rule (88 FR 79168), these services would be provided in conjunction with professional services, such as Evaluation and Management visits, which can be provided in a primary care setting. Additionally, these are separately payable services when provided with an Annual Wellness Visit (AWV) and the AWV is included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment. Finally, these services precede the utilization of Community Health Integration, Principal Illness Navigation, and Care Management services which are currently included in the definition of primary care services used for purposes of assignment under § 425.400.

Comment: Many commenters requested that HCPCS code G0136 not be removed from the definition of primary care services for purposes of assignment if CMS finalizes its proposal to delete HCPCS code G0136. The commenters stated that they are opposed to the removal of HCPCS code G0136 from the definition of primary care services because they are more broadly opposed to the deletion of the code from HCPCS code set. The commenters requested that HCPCS code G0136 not be deleted so there

will not be a need to remove HCPCS code G0136 from the definition of primary care services.

Response: As described in section II.I of this final rule, CMS has decided not to finalize our proposal to delete HCPCS code G0136. We are instead revising the code descriptor to the following text: *G0136 – [Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5-15 minutes, not more often than every 6 months].* Since HCPCS code G0136 is not being deleted and it remains a payable service under the PFS, we will not remove the code from the definition of primary care services used for purposes of assignment.

After consideration of public comments, we are finalizing as proposed the revised definition of primary care services used for assignment for the performance year starting on January 1, 2026, and subsequent performance years in a new provision of the Shared Savings Program at § 425.400(c)(1)(x) to include the list of HCPCS and CPT codes specified at § 425.400(c)(1)(ix), as well as the following additions: Enhanced Care Model Management Services (HCPCS codes (GPCM1, GPCM2, and GPCM3 which are being finalized as G0568, G0569, and G0570, respectively), and we are not finalizing the proposal to delete HCPCS code G0136 from the definition of primary care services. We are instead revising the code descriptor for HCPCS code G0136, which will describe physical activity and nutrition assessment services in the revised definition of primary care services. Additionally, we are finalizing as proposed the incorporation of a provision at § 425.400(c)(1)(x)(C), specifying that primary care service codes used for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified at § 425.400(c)(1)(x)(A) or a HCPCS code specified at § 425.400(c)(1)(x)(B), when the assignment window or expanded window for assignment (as defined at § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under Medicare FFS.

Further, the text of the proposed regulations in the CY 2026 PFS proposed rule (90 FR 32854 through 32855) included a proposed technical modification to the introductory text in § 425.400(c)(1)(ix), to limit the applicability of that provision to the performance year starting on January 1, 2025. This change is necessary so that we can effectuate § 425.400(c)(1)(x) as explained in the proposed rule and its regulatory text: to apply for the performance year starting on January 1, 2026, and subsequent performance years. We received no comments addressing the proposed technical modification to

§ 425.400(c)(1)(ix), and we are finalizing this change without modification.

6. Quality Performance Standard & Other Quality Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality healthcare at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care and wherever practicable, caregiver experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, 2021, 2023, 2024, and 2025 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80489, 83 FR 59708 through 59715, 85 FR 84733 through 84734, 87 FR 69860 through 69863, 88 FR 79112 through 79114, and 89 FR 98124 through 98132, respectively).

b. Revising the Definition of a "Beneficiary Eligible for Medicare CQMs"

(1) Background

In the CY 2026 PFS proposed rule (90 FR 32673 and 32674), we stated that in the CY 2024 PFS final rule (88 FR 79097 through 79107), for performance year 2024 and subsequent performance years, we established Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs within the APP quality measure set and for which the ACO reports quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20. This option has allowed and continues to allow ACOs to develop experience aggregating data for their Medicare fee-for-service (FFS) patients across their participant TINs and provides ACOs with opportunities to develop workflows to allow them to transition to reporting quality data for their entire population through digital quality measurement.

As stated in the CY 2024 PFS final rule (88 FR 79101), Medicare CQMs have served and continue to serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment. Specifically, Medicare CQMs addressed the concern raised by ACOs that for ACOs with a higher proportion of specialty practices, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, given ACOs are commonly made up of multiple practices using multiple EHRs, ACOs have been able to utilize Medicare Part A and B claims data to help identify the ACO's eligible population and validate the ACO's patient matching and deduplication efforts. We also stated that Medicare CQMs are an all-beneficiary Medicare measure (not just ACO assigned beneficiaries) and are designed to help ACOs address challenges with aggregating patient data required to report Medicare CQMs and the all payer/all patient MIPS CQMs and eCQMs in the future (88 FR 79102).

In the CY 2024 PFS final rule (88 FR 79107), we also finalized the definition of a "beneficiary eligible for Medicare CQMs" at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

- A Medicare FFS beneficiary (as defined at § 425.20) who –

++ Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

++ Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

- A Medicare FFS beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

We discussed in the CY 2024 PFS final rule that, in response to our proposed definition of a "beneficiary eligible for Medicare CQMs" in the CY 2024 PFS proposed rule, many commenters raised

questions and concerns regarding how CMS will determine the appropriate Medicare CQM population for these measures (88 FR 79102). Some commenters noted that the proposed denominator eligibility criteria are similar to, but differ in timeline from, the current assignment methodology and that this creates unnecessary complexity, potentially leading to concerns in identifying the appropriate Medicare ACO population. A few commenters suggested we combine the new Medicare CQM methodology with the existing assignment methodology, which would mitigate potential challenges and ensure a smoother implementation process. Several commenters requested that we clarify if the list of "beneficiaries eligible for Medicare CQMs" is limited to assigned beneficiaries or if it includes all assignable beneficiaries eligible for the measure.

In the CY 2024 PFS final rule (88 FR 79102), in response to commenters' suggestions to align the definition of "beneficiary eligible for Medicare CQM" with our assignment methodology, we noted that our definition of a beneficiary eligible for Medicare CQMs aims to align Medicare CQMs with the all payer/all patient measure specifications because Medicare CQMs are intended to support ACOs in the transition to all payer/all patient measures. We stated that the definition would limit Medicare CQM reporting to beneficiaries that had an encounter with an ACO professional with a specialty used in assignment or who were voluntarily assigned to the ACO. We noted that our approach would also balance our commitment to the transition to all payer/all patient measures with the need to provide additional support to some ACOs as they build the skills and infrastructure necessary to report digital quality measures.

To support ACOs in reporting Medicare CQMs, we finalized that we would provide each ACO with a list of beneficiaries eligible for Medicare CQMs each quarter throughout the performance year as part of the ACO's Quarterly Informational Reports Packages to give ACOs access to the full 12 months of encounters necessary to report Medicare CQMs (88 FR 79104 and 79105). We stated that the list would be cumulative and updated quarterly to reflect the most recent quarter's data, and the fourth quarter list of beneficiaries eligible for Medicare CQMs would include encounters with dates of service January 1st through December 31st of the performance year. We stated that the quarterly list would include beneficiary-level age, diagnosis, encounter, and exclusion flags on the list of beneficiaries eligible for Medicare CQMs to aid ACOs in identifying the denominator eligible population for each measure to the

extent that such data can be identified through claims and Medicare administrative systems. We also stated that it was important to note that these flags are meant to assist ACOs in the aggregation of data and do not replace the need for ACOs to evaluate their patient population against each Medicare CQM specification prior to submission, including determining the beneficiaries that meet the denominator criteria for the measure. We now note, by way of additional explanation, that since the list does not apply measure-specific eligibility criteria, the list may include Medicare FFS beneficiaries who are not eligible for inclusion in any of the three Medicare CQMs in the APP quality measure set.

Based on our experience with providing ACOs with the quarterly lists of beneficiaries eligible for Medicare CQMs for performance year 2024, we have learned that the complexity of the current definition of a "beneficiary eligible for Medicare CQMs" has continued to create confusion for some Shared Savings Program ACOs. Some of these ACOs have sought additional clarification and guidance from CMS. Revising the definition of a "beneficiary eligible for Medicare CQMs" would be responsive to these ACOs and other feedback from interested parties and would reduce ACOs' burden with respect to the patient matching necessary to report Medicare CQMs. Some of the ACO feedback we have received has been based on the differences between the Medicare CQM beneficiary lists that they have received from CMS and the assignable or assigned beneficiary files that ACOs also receive from CMS. Differences in the beneficiary information obtained from these files has contributed to concerns from ACOs about which beneficiaries to use for quality data reporting through Medicare CQMs.

The methodology used to generate the list of "beneficiaries eligible for Medicare CQMs" differs from the methodology described at §§ 425.400, 425.401, 425.402, and 425.404 used to generate the list of beneficiaries assignable to an ACO, that is the universe of beneficiaries who receive at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). These methodologies differ in time frames and encounter codes used, which has led to inquiries by ACOs and increased burden due to marginal differences in overlapping populations that meet these criteria. Our current definition of a "beneficiary eligible for Medicare CQMs" was intended to create alignment with the all payer/all patient MIPS CQM Specifications. The use of the terms of "claim" and "measurement period" in the definition of a "beneficiary eligible for Medicare CQMs" are consistent

with the application of all payer/all patient MIPS CQM Specifications. The codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications only partially overlap with the HCPCS and revenue center codes designated at § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program. Similarly, the measurement period applicable to each measure in the all payer/all patient MIPS CQM Specifications only partially overlaps with the 12-month period used in assignment (88 FR 79098). These differences mean an ACO may have beneficiaries eligible for Medicare CQMs that are not part of an ACO's assigned or assignable population. For example, this may occur if the beneficiary has a claim by an ACO professional or specialty designation that is not a primary care service or a claim that occurs during the measurement period but outside the assignment window.

(2) Revisions

In the CY 2026 PFS proposed rule (90 FR 32674 through 32676), we stated that considering the concerns raised by ACOs and other interested parties, and our commitment to supporting ACOs in the transition to digital quality measure reporting, we proposed to revise the definition of a "beneficiary eligible for Medicare CQMs" at § 425.20 effective January 1, 2025, meaning we proposed to apply the revised definition for performance year 2025, as well as for subsequent performance years. Specifically, beginning with performance year 2025 and continuing in subsequent performance years, we proposed to revise the definition to require, in (1)(ii)(B) of the definition, "at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist." We would redesignate the existing (1)(ii) as (1)(ii)(A). The current definition of "beneficiary eligible for Medicare CQMs" requires, in (1)(ii), "at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist." For performance year 2025 and subsequent performance years, the revised definition we proposed in (1)(ii)(B) would align with our modifications to the stepwise assignment methodology and approach to identifying the beneficiaries assignable to an ACO, as finalized in the CY 2024 PFS final rule (88 FR 79162) and described at §

425.402(a)(5), where physician assistants, nurse practitioners, and clinical nurse specialists were added to the process for identifying beneficiaries assignable to an ACO beginning in performance year 2025. Specifically, the revised definition we proposed in (1)(ii)(B) uses "primary care services" and "performance year," instead of "claims" and "measurement period," respectively, as used in the current definition. The proposed definition in (1)(ii)(B) would continue to align with the special assignment conditions for ACOs, including Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs), as described at § 425.404. We provide a list of "beneficiaries eligible for Medicare CQMs" to each ACO. We would continue to include on that list all beneficiaries for whom a service is reported on an FQHC/RHC claim. As described at § 425.404, we treat a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

The proposal to revise the definition of a "beneficiary eligible for Medicare CQMs" would reduce ACOs' burden in the patient matching necessary to report Medicare CQMs because the list of "beneficiaries eligible for Medicare CQMs" would have greater overlap with the list of beneficiaries that are assignable to an ACO. Specifically, more closely aligning these definitions would mean that, for most ACOs, the large majority of an ACO's beneficiaries eligible for Medicare CQMs would be part of the list of beneficiaries assignable to an ACO. Therefore, under the proposed definition of a "beneficiary eligible for Medicare CQMs," most ACOs would have to do less patient matching than they presently do because there would be fewer differences between the definition of "beneficiary eligible for Medicare CQMs" and "assignable beneficiary." The proposal would also help each ACO identify its eligible population and validate the ACO's patient matching and deduplication efforts because ACOs would see fewer differences between the Medicare CQM beneficiary list and the list of beneficiaries assignable to the ACO. We believe our proposal to revise the definition of a "beneficiary eligible for Medicare CQMs" would substantially address ACOs' and interested parties' concerns by better aligning the definitions and clarifying which beneficiaries' data to use for quality data reporting through Medicare CQMs.

We conducted a gap analysis using performance year 2024 data to analyze the overlap of our proposed definition of a "beneficiary eligible for Medicare CQMs" and the current performance year 2025 methodology used to identify beneficiaries assignable to an ACO. The goal of this analysis was to determine whether the proposed change in the definition of a "beneficiary eligible for Medicare CQMs"

would accomplish our goal of aligning that population with the list of beneficiaries assignable to an ACO. With the addition of physician assistants, nurse practitioners, and clinical nurse specialists beginning in performance year 2025 for identifying assignable beneficiaries, as well as the proposed change to the definition of a "beneficiary eligible for Medicare CQMs" to require "primary care services," the overlap between the Medicare CQM eligible population and the list of beneficiaries assignable to an ACO is expected to increase, on average, to 85 percent for most ACOs. We note that the amount of overlap between assignable beneficiaries and beneficiaries eligible for Medicare CQMs will vary across ACOs due to factors like different population composition and different use patterns of non-physician care codes. Overall, we believe that the proposed changes will generally help ACOs identify and collect data for the population of beneficiaries eligible for Medicare CQMs and support adoption of Medicare CQMs. Therefore, we proposed to revise the definition of a "beneficiary eligible for Medicare CQMs," at § 425.20, for performance year 2025 and subsequent performance years, to require at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

To support ACOs in preparing for this proposed change, we will continue to provide the quarterly list based on the definition of a "beneficiary eligible for Medicare CQMs" as finalized in the CY 2024 PFS final rule (88 FR 79097 through 79107) and will add an additional variable to the quarterly list to flag each beneficiary who had a primary care service visit, beginning with the performance year 2025 Quarter 2 list, to identify "beneficiaries eligible for Medicare CQMs" under the proposed definition. We further noted that if this proposal were to be finalized, then the quarterly list, starting with performance year 2025 Quarter 4, would be based on the finalized definition of a "beneficiary eligible for Medicare CQMs."

In the CY 2026 PFS proposed rule (90 FR 32675), we stated that section 1871(e)(1)(A) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. It is in the public interest to apply our proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" beginning in

performance year 2025. Applying these changes starting with performance year 2025 is in the public interest because, absent the proposed changes in the definition, the current definition is an ongoing contributor to ACOs' confusion regarding which beneficiaries to use for quality data reporting through Medicare CQMs and creates burden for ACOs in patient matching and quality reporting. Minimizing this complexity through our proposed changes in definition will reduce the burden on ACOs that elect to report Medicare CQMs and better enable them to gain experience with aggregating and deduplicating data, since Medicare CQMs are intended to aid in the transition to digital quality measure reporting quality data for an ACO's entire population. The proposed changes to the definition, and resulting burden reduction, will allow ACOs to devote greater resources to improving care coordination so that they are better positioned to deliver the right care at the right time, all to the benefit of Medicare beneficiaries served by the ACO and Medicare Trust Funds. We believe the proposed changes would have minimal impact on ACOs' existing processes because the ACO would continue to apply the measure specifications to the population of beneficiaries eligible for Medicare CQMs, but the beneficiary population would be based on a list of beneficiaries that better reflects the ACO's assigned population.

We proposed to revise the definition of "Beneficiary eligible for Medicare CQMs" at § 425.20, as follows:

- We added a new paragraph (A) to paragraph (1)(ii) of the definition of "beneficiary eligible for Medicare CQMs" at § 425.20 to establish that, in addition to the requirement in paragraph (1)(i) and for performance year 2024, a beneficiary eligible for Medicare CQMs "had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist."[413] This proposal would effectively move the existing text of paragraph (1)(ii) to paragraph (1)(ii)(A) and limit the application of the existing text of paragraph (1)(ii) to performance year 2024.

- We added a new paragraph (B) to paragraph (1)(ii) of the definition of "beneficiary eligible for Medicare CQMs" at § 425.20 to establish that, in addition to the requirement in paragraph (1)(i) and for

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[413] In quoting the language from the proposed §§ 425.20(1)(ii)(A) and 425.20(1)(ii)(B) respectively, we inadvertently made a typographical error in the preamble and used the term "at" instead of "in" when referring to § 425.402(c). We intended for this text to mirror the text from the proposed §§ 425.20(1)(ii)(A) and 425.20(1)(ii)(B), respectively (90 FR 32676).

performance year 2025 and subsequent performance years, a beneficiary eligible for Medicare CQMs "had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist."

We sought public comments on the proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" at § 425.20.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposal to revise the definition of a "beneficiary eligible for Medicare CQMs" to more closely align with the definition of an "assignable beneficiary" under the Shared Savings Program. Several commenters supported that we proposed to have the changes go into effect beginning with performance year 2025, which should alleviate some of the burden ACOs face in reporting Medicare CQMs for performance year 2025.

Some commenters thanked CMS for being responsive to concerns from interested parties. Some commenters stated that the current definition of a "beneficiary eligible for Medicare CQMs" has created confusion and that the proposed changes should alleviate some of the confusion created by differences in the Medicare CQM beneficiary lists and the assignable beneficiary lists that ACOs receive from CMS. Several commenters stated the proposed changes will reduce burden for ACOs reporting Medicare CQMs, such as reducing the ACO's burden in identifying the eligible population, validating the ACO's patient matching, and deduplicating patient data, which are necessary steps to report Medicare CQMs.

A commenter supported the proposal as it addresses concerns of ACOs that have many specialists that do not provide primary care services and noted that otherwise it would be unduly burdensome to report measures that are not addressed by these specialists. Other commenters stated the proposed change helps ACOs focus on patient care and streamline reporting across various EHRs and practices and recognizes the reporting challenge ACOs have faced transitioning to eCQMs. A commenter stated that the proposed changes will enhance Fast Healthcare Interoperability Resources® (FHIR®) connectivity with practices, while another commenter stated that it will support the ACO's transition to digital quality measure reporting.

Response: We thank commenters for their support of our proposal to revise the definition of a "beneficiary eligible for Medicare CQMs" for performance year 2025 and subsequent performance years.

Comment: A commenter recommended delaying implementation of the proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" until 2026 to allow sufficient time for planning and system updates.

Response: We stated in the CY 2026 PFS proposed rule (90 FR 32675 and 32676) that it is in the public interest to apply our proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" beginning in performance year 2025 because, absent the proposed changes in the definition, the current definition is an ongoing contributor to ACOs' confusion regarding which beneficiaries to use for quality data reporting through Medicare CQMs and creates burden for ACOs in patient matching and quality reporting. Additionally, CMS has supported ACOs in preparing for this proposed change by adding an additional variable to the quarterly list, beginning in performance year 2025 Quarter 2, to flag each beneficiary who had a primary care service visit to identify "beneficiaries eligible for Medicare CQMs" under the proposed definition. The performance year 2025 Quarter 2 quarterly list with this additional information was shared with ACOs on August 25, 2025 to help ACOs prepare for this proposed change. The Medicare CQM quarterly list, starting no later than performance year 2025 Quarter 4, will be based on the finalized definition of a "beneficiary eligible for Medicare CQMs." We believe the proposed changes would have minimal impact on ACOs' existing processes and will not require system updates or substantial additional planning because the ACO would continue to apply the measure specifications to the population of beneficiaries eligible for Medicare CQMs, but the beneficiary population would be based on a list of beneficiaries that better reflects the ACO's assigned population.

Comment: Several commenters supported our proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" but also stated that the changes do not resolve challenges for ACOs that use preliminary prospective assignment with retrospective reconciliation. Commenters noted that these ACOs receive claims data only for their attributed population, but under CMS' proposal, they may be required to report Medicare CQMs for "attributable" beneficiaries outside of the ACO's care.

A few commenters expressed concern that ACOs would have to report on beneficiaries that are not aligned to their organization. Another commenter stated that their providers were negatively impacted

by beneficiaries counting in the numerator whom they had never seen or had not seen in the performance year.

Some commenters recommended that CMS: 1) expand the claims data they share with ACOs to include "attributable" beneficiaries, regardless of attribution methodology; and/or 2) require Medicare CQMs be reported for "attributed" beneficiaries only.

Response: In response to comments that stated our proposal does not resolve challenges for ACOs that use preliminary prospective assignment with retrospective reconciliation, we note that our proposed revised definition of a "beneficiary eligible for Medicare CQMs" is the same for ACOs under preliminary prospective assignment with retrospective reconciliation and ACOs under prospective assignment. As stated in the CY 2024 PFS final rule, a Medicare CQM is essentially a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare FFS beneficiaries, instead of its all payer/all patient population (88 FR 79098). In a manner that is identical to the MIPS CQM specifications, the Medicare CQM Specifications will be applied in the same way regardless of the ACO's assignment election. Medicare CQMs are designed to help ACOs address challenges with aggregating patient data required to report the all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that is broader than the assigned population but exists within the all payer/all patient MIPS CQM specification (88 FR 79102). Regarding concerns that ACOs would have to report on beneficiaries not seen by their providers, we note that the Medicare CQM population is tethered to claims encounters with ACO professionals with specialties used in assignment, which limits the ACO's quality reporting to patients with a care relationship with the ACO (88 FR 79102).

We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure.

Regarding comments suggesting that CMS expand the claims data they share with ACOs, we note that CMS provides quarterly lists for all beneficiaries eligible for Medicare CQM reporting based on available claims data. Additionally, we note that the Medicare CQM collection type allows for the use of multiple sources of data (for example, multiple EHRs, paper records, registries, patient management systems) to compile a measure's numerator and denominator. Although claims data can be helpful to ACOs, claims data does not replace medical record documentation of care provided by the ACO or

patient care coordinated by ACO providers with other providers outside the ACO at the point of care. To successfully report Medicare CQMs, ACOs need to use available documentation of care provided at the point of care and be able to provide medical record documentation that supports the quality action that was performed.

Comment: A commenter opposed the inclusion of physician assistants, nurse practitioners, and clinical nurse specialists as primary care providers to the definition of a "beneficiary eligible for Medicare CQMs". The commenter recommended that physician assistants, nurse practitioners, and clinical nurse specialists should only be deemed a primary care provider if they deliver care in a primary care practice.

Response: As stated in the CY 2026 PFS proposed rule (90 FR 32675), for performance year 2025 and subsequent performance years, the revised definition we proposed in (1)(ii)(B) of the definition of a "beneficiary eligible for Medicare CQMs" would align with our modifications to the stepwise assignment methodology and approach to identifying the beneficiaries assignable to an ACO, as finalized in the CY 2024 PFS final rule (88 FR 79162) and described at § 425.402(a)(5), where physician assistants, nurse practitioners, and clinical nurse specialists were added to the process for identifying beneficiaries assignable to an ACO beginning in performance year 2025. We clarify that the definition of a "beneficiary eligible for Medicare CQMs" currently in § 425.20 already includes physician assistants, nurse practitioners, and clinical nurse specialists. Under the revised definition of a "beneficiary eligible for Medicare CQMs," physician assistants, nurse practitioners, and clinical nurse specialists continue to be considered ACO professionals, but must have provided a primary care service. CMS did not, contrary to the commenter's understanding, propose defining or deeming them to be "primary care providers." Additionally, the primary care services provided by physician assistants, nurse practitioners, and clinical nurse specialists have been used in the Shared Savings Program assignment methodology (§ 425.402) since the inception of the program. Revising the definition of a "beneficiary eligible for Medicare CQMs" to include primary care services provided by physician assistants, nurse practitioners, and clinical nurse specialists would further our intent of aligning this definition with our long-standing inclusion of these providers in the program's assignment methodology.

As discussed in the CY 2024 final rule (88 FR 79103), we recognize that care is delivered to beneficiaries by a range of clinicians. ACOs that include specialists included in the "beneficiary eligible

for Medicare CQMs" definition would need to collect data from those specialists to submit true, accurate, and complete data when reporting Medicare CQMs. We will provide ACOs with a list of beneficiaries eligible for Medicare CQMs that can be used by ACOs to identify encounters with specialists that should be included in quality measure reporting and improvement.

Comment: A few commenters suggested that CMS should limit reporting of Medicare CQMs to the patients included on the Medicare CQM list issued by CMS to ACOs.

Response: The quarterly list of the ACO's beneficiaries eligible for Medicare CQMs includes Medicare FFS beneficiaries who are eligible for Medicare CQM reporting by the ACO. These files are cumulative (year to date) and updated quarterly to reflect the most recent quarter's data. For example, the list of beneficiaries eligible for Medicare CQMs for Quarter 4 of performance year 2025 will include all Medicare FFS beneficiaries who are eligible for Medicare CQM reporting, based on available claims data for encounters with dates of service from January 1 through December 31. The list will include beneficiaries that meet any of the measure-specific eligibility criteria; therefore, it may include Medicare FFS beneficiaries who are not eligible for inclusion in any of the four Medicare CQMs in the APP Plus quality measure set for performance year 2025. ACOs must determine eligibility for each Medicare CQM by applying the measure specifications to the Quarter 4 list, if they choose to use it, to ensure measure inclusion and exclusion criteria are captured accurately. We direct readers to our guidance on the submission of Medicare CQMs. Specifically, the 2025 Medicare CQM Checklist for Shared Savings Program Accountable Care Organizations, which is posted in the QPP Resource Library *at https://qpp-cm-prodcontent.s3.amazonaws.com/uploads/3266/PY2025MedicareCQMChecklist%20%28002%29.pdf* and the Medicare CQM Reporting by Shared Savings Program ACOs: Frequently Asked Questions, which is posted in the QPP Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3175/Medicare-CQM-FAQs.pdf*.

Comment: A commenter stated that the quarterly Medicare CQM lists are delayed, limiting ACOs' ability to guide reporting in real time and increasing the risk of inaccuracies.

Response: To support ACOs in reporting Medicare CQMs, we finalized in the CY 2024 PFS final rule (88 FR 79104 and 79105) that we will provide each ACO with a list of beneficiaries eligible for Medicare CQMs each quarter throughout the performance year as part of the ACO's Quarterly

Informational Reports Packages to give ACOs access to the full 12 months of encounters necessary to report Medicare CQMs. The list will be cumulative and updated quarterly to reflect the most recent quarter's data. We note that the PY 2025 Medicare CQM quarterly lists have followed the release schedule of prior years with no delays. For example, encounters with dates of service January 1st through March 31st of the performance year are included in the Quarter 1 list. Quarter 1 report packages are typically delivered to ACOs in May of the performance year. The Quarter 2 list includes encounters with dates of service January 1st through June 30th of the performance year. Quarter 2 report packages are typically delivered to ACOs in August of the performance year. The Quarter 3 list includes encounters with dates of service January 1st through September 30th of the performance year. Quarter 3 report packages are typically delivered to ACOs in November of the performance year. Lastly, the Quarter 4 list of all of the ACO's beneficiaries eligible for Medicare CQMs includes encounters with dates of service January 1st through December 31st of the performance year. Quarter 4 report packages are typically delivered to ACOs in February of the year following the performance year. The Quarter 4 list includes all of the ACO's Medicare CQM eligible beneficiaries.

The cadence of updating the list throughout the performance year will enable ACOs to aggregate data throughout the performance year, prepare the majority of their submission data in advance of the submission period, and then use the Quarter 4 list to ensure that all beneficiaries that are eligible for Medicare CQMs are captured in the ACOs' reporting.

Comment: A commenter requested that CMS provide more robust demographics to assist with patient matching for ACOs reporting Medicare CQMs, such as patient addresses.

Response: We thank the commenter for their suggestion and may take it into consideration for future updates to the Medicare CQM quarterly lists.

Comment: A commenter requested clarification on whether ACOs have an obligation to report on beneficiaries without a PCS_Encounter field and whether beneficiaries that lacked a value for the PCS_Encounter field will be removed from the quarterly Medicare CQM list going forward.

Response: We stated in the CY 2026 PFS proposed rule (90 FR 32675) that, if this proposal is finalized, then the quarterly list, starting with performance year 2025 Quarter 4, would be based on the finalized definition of a "beneficiary eligible for Medicare CQMs." As discussed below, we are finalizing

our proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" effective January 1, 2025. The ACO will not have an obligation to report on beneficiaries without a PCS_Encounter field because those beneficiaries have not had a primary care service. The Medicare CQM quarterly list, starting no later than performance year 2025 Quarter 4, will be based on the finalized definition of a "beneficiary eligible for Medicare CQMs," including removal of the PCS_Encounter field. This means that only beneficiaries that had at least one primary care service encounter during the List Period will be included in the Medicare CQM Quarterly List.

Comment: A commenter disagreed that MIPS CQM and Medicare CQM reporting options are similar or easily interchangeable and referenced ongoing challenges ACOs encounter transitioning to Medicare CQMs. The commenter recommended that CMS extend MIPS CQM reporting past performance year 2026 and offer incentives for all payer reporting.

Response: As stated in the CY 2024 PFS final rule (88 FR 79098) and the CY 2025 PFS final rule (89 FR 98107), a Medicare CQM is essentially a MIPS CQM reported by an ACO under the APP (for performance year 2024 or earlier) or the APP Plus quality measure set, where the only difference is the patient universe. Medicare CQMs are limited to only the ACO's Medicare FFS beneficiaries (as defined at § 425.20), while MIPS CQMs include all patients regardless of their payer. The Medicare CQM and MIPS CQM Specifications are otherwise identical, including their numerators, denominators, and exclusions. We anticipate that ACOs with the infrastructure to report MIPS CQMs can readily transition to report Medicare CQMs. As stated in the CY 2024 PFS final rule (88 FR 79105), in a manner identical to MIPS CQM Specifications, the Medicare CQM Specifications will allow for the use of multiple sources of data (for example, multiple EHRs, paper records, registries, patient management systems) to compile a measure's numerator and denominator. We believe that ACOs with the experience or technical infrastructure to report MIPS CQMs may employ the same processes to report Medicare CQMs so long as the Medicare CQM population meets the definition of a "beneficiary eligible for Medicare CQMs."

Regarding the commenter's suggestion that CMS extend MIPS CQM reporting past performance year 2026, we note that we also stated that while we continue to believe that Medicare CQMs are a valuable transition step on our building-block approach for Shared Savings Program ACOs' progress to adopt digital quality measurement, under the policies we finalized in the CY 2025 PFS final rule (89 FR

98107), Shared Savings Program ACOs would continue to have the option to report the APP Plus quality measures using the MIPS CQM collection type for performance years 2025 and 2026. In addition, we extended the reporting incentive for ACOs reporting MIPS CQMs through performance year 2026. We further noted that this additional time would further allow ACOs to address challenges and burdens they may face when reporting Medicare CQMs. Therefore, for performance years 2025 and 2026, Shared Savings Program ACOs that report the APP Plus quality measure set will have the option to use any of the following collection types or a combination thereof, as applicable: Medicare CQM, MIPS CQM and eCQM. As we stated in the CY 2025 PFS final rule (89 FR 98108), the collection types available to ACOs reporting the APP Plus quality measure set for performance year 2025 and subsequent years recognize the need for some ACOs to build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures while incentivizing ACOs to transition to eCQMs. We will continue to monitor ACOs' experience and uptake of collection types in the coming years.

Comment: A commenter encouraged CMS to use this opportunity to explore how digital quality measurement (dQMs) could be integrated into the existing reporting requirements for ACOs.

Response: We remain committed to the transition to dQMs. We refer readers to the CY 2026 PFS proposed rule (90 FR 32710-32715), which contains a Request for Information to gather public input on the transition to dQM for CMS programs and on our anticipated approach on the use of FHIR® standards in eCQM reporting. In that section, we described the current state and requested input on key components of the ongoing dQM transition related to FHIR®-based eCQMs for the Shared Savings Program and the MIPS quality performance category. These components include: (1) FHIR®-based eCQM conversion progress; (2) Data standardization for quality measurement and reporting; (3) The timeline under consideration for FHIR®-based eCQM reporting; (4) Measure development and reporting tools; and (5) FHIR® Reporting and Data Aggregation for ACOs.

Comment: Several commenters expressed concerns about the continued technical challenges with reporting Medicare CQMs. A commenter noted the inherent complexities with registry development and incompatible EHR systems. They further noted that reporting Medicare CQMs also adds operational burden for ACOs as many EHR systems cannot effectively identify and separate these patient groups. Another commenter noted the significant amount of resources required to transition to Medicare CQMs,

vendor struggles with incorporating Medicare CQMs into their software platforms, and some vendors' inability to support Medicare CQMs in 2025.

Response: While these comments are out of scope for this final rule, we acknowledge commenters' concerns with identifying patients, operationalizing Medicare CQMs, and with having vendor issues. We will continue to support and provide guidance to ACOs reporting Medicare CQMs consistent with measure specifications. We further direct readers to our guidance on the submission of Medicare CQMs. Specifically, we direct readers to the 2025 Medicare CQM Checklist for Shared Savings Program Accountable Care Organizations, which is posted in the QPP Resource Library at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3266/PY2025MedicareCQMChecklist%20%28002%29.pdf, and the Medicare Shared Savings Program: 2024 Reporting eCQMs, MIPS CQMs, and Medicare CQMs in the APP (guidance document), which is posted in the QPP Resource Library at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3124/MSSP-2024-Reporting-eCQMs-MIPS-CQMs-and-Medicare-CQMs-in-the-APP.pdf, for resources and support for reporting eCQMs, MIPS CQMs, and Medicare CQMs. We also encourage ACOs and their vendors to participate in our monthly QCDR and Qualified Registry support calls, Learning System Webinars and to submit questions to the Shared Savings Program helpdesk via ACO-MS, as needed.

After consideration of public comments, we are finalizing as proposed changes to the definition of a "beneficiary eligible for Medicare CQMs" at § 425.20, effective January 1, 2025. Specifically, we are finalizing the following revisions to the definition of "beneficiary eligible for Medicare CQMs" at § 425.20:

- We are adding a new paragraph (A) to paragraph (1)(ii) of the definition of "beneficiary eligible for Medicare CQMs" at § 425.20 to establish that, in addition to the requirement in paragraph (1)(i) and for performance year 2024, a beneficiary eligible for Medicare CQMs "had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist." This change would effectively move the existing text of paragraph (1)(ii) to paragraph (1)(ii)(A) and limit the application of the existing text of paragraph

(1)(ii) to performance year 2024.

- We are adding a new paragraph (B) to paragraph (1)(ii) of the definition of "beneficiary eligible for Medicare CQMs" at § 425.20 to establish that, in addition to the requirement in paragraph (1)(i) and for performance year 2025 and subsequent performance years, a beneficiary eligible for Medicare CQMs "had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist."

c. Removing the Health Equity Adjustment Applied to an ACO's Quality Score and Revising Certain Terminology in the Shared Savings Program Regulations

(1) Background

In the CY 2026 PFS proposed rule (90 FR 32676 and 32677), we stated that in the CY 2023 PFS final rule (87 FR 69838 through 69857), we finalized a health equity adjustment that, for performance year 2023 and subsequent performance years, would be available to an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey. We finalized that such ACOs may receive up to a maximum of 10 additional points added to their MIPS quality performance category score. The level of the adjustment is based on the joint consideration of an ACO's performance on quality measures and the population served by the ACO, such that ACOs that perform well on quality measures and serve a high proportion of beneficiaries who are from underserved neighborhoods (residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85); or who are eligible for the Medicare Part D Low-Income Subsidy (LIS), or are dually eligible for Medicare and Medicaid would receive a higher number of bonus points added to their MIPS quality performance category score. In the CY 2024 PFS final rule (88 FR 79110 and 79111), we finalized that ACOs reporting Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score.

In the CY 2026 PFS proposed rule (90 FR 32676), we explained that the health equity adjustment was designed to further several goals, including supporting ACOs transitioning to all payer/all patient

quality measure reporting, incentivizing ACOs to report eCQMs/MIPS CQMs/Medicare CQMs, improving quality, and recognizing high-performing ACOs serving underserved populations (See 87 FR 69841 and 69842; 88 FR 79097). The regulation at § 425.512(b) specifies how we calculate an ACO's health equity adjusted quality performance score for performance year 2023, performance year 2024, and performance year 2025 and subsequent performance years. We noted that we had also incorporated references to an ACO's health equity adjusted quality performance score at §§ 425.512(a), 425.512(c), 425.605(d), and 425.610(d) and (f), as applicable.

In the CY 2025 PFS final rule, we established or extended additional scoring adjustments for ACOs, such as the Complex Organization Adjustment (89 FR 98116 and 98117 and 89 FR 98105) and the eCQM/MIPS CQM reporting incentive (89 FR 98121 through 98124), respectively.

Complex Organization Adjustment: In the CY 2025 PFS final rule (89 FR 98116 and 98117), we established a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year to account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs. A Virtual Group and an APM Entity will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Each reported eCQM may not score more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment will be added for each eCQM submitted at the individual measure level. Since Shared Savings Program ACOs are APM Entities, this policy is applicable to Shared Savings Program ACOs reporting the APP Plus quality measure set beginning in performance year 2025.

eCQM/MIPS CQM Reporting Incentive: We originally adopted an incentive for ACOs to begin transitioning to eCQM/MIPS CQM reporting (herein referred to as the "eCQM/MIPS CQM reporting incentive") in the CY 2022 PFS final rule (86 FR 65261 and 65262). In the CY 2023 PFS final rule, we extended the eCQMs/MIPS CQM reporting incentive through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year

to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures are required beginning in performance year 2025 (87 FR 69836 through 69838). We further extended the eCQM/MIPS CQM reporting incentive in the CY 2025 PFS final rule (89 FR 98124) to continue to support ACOs in the transition to eCQMs for digital quality measurement reporting. Meeting the criteria for the eCQM/MIPS CQM incentive allows an ACO to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

As we stated in the CY 2026 PFS proposed rule (90 FR 32676 and 32677), the extension of the eCQM/MIPS CQM reporting incentive ensures continued support for ACOs as they gain experience reporting all payer/all patient measures. Specifically, for performance year 2025 and subsequent performance years for ACOs reporting eCQMs, and performance years 2025 and 2026 for ACOs reporting MIPS CQMs, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the MIPS data completeness requirement for all eCQMs/MIPS CQMs;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set; and
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set (89 FR 98122 through 98124).

We stated in the CY 2025 PFS final rule (89 FR 98123) that we believe the increased number of quality measures that will be phased into the APP Plus quality measure set over time will afford ACOs expanded opportunities to satisfy the eCQM/MIPS CQM reporting incentive criteria. For instance, the number of eCQMs/MIPS CQMs in the APP Plus quality measure set will increase from four in performance year 2025 to five in performance year 2026. Once MIPS CQMs are removed from the APP Plus quality measure set in performance year 2027, the number of eCQMs in the APP Plus quality measure set will increase from 5 to 6 in performance year 2027. With the finalized removal of Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in section

III.F.6.d. of this final rule, once all of the eCQMs are incorporated into the APP Plus quality measure set, there would be seven eCQMs. Out of these seven eCQMs, two of them (Quality ID: 001 Diabetes: Glycemic Status Assessment Greater Than 9% and Quality ID: 236 Controlling High Blood Pressure) are outcome measures and focus on the management of chronic conditions. There are also three eCQMs (Quality ID: 112 Breast Cancer Screening, Quality ID: 113 Colorectal Cancer Screening, and Quality ID: 493 Adult Immunization Status) that focus on wellness and prevention.

(2) Removing the Health Equity Adjustment Applied to an ACO's Quality Score

In the CY 2026 PFS proposed rule (90 FR 32677 through 32679), we stated that after further consideration and experience implementing the eCQM/MIPS reporting incentive and the Complex Organization Adjustment, in conjunction with the previous policies we have finalized with respect to the health equity adjustment, we have concluded that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment provide duplicative incentives to the health equity adjustment for ACOs to meet the quality performance standard under the Shared Savings Program.

As described in the CY 2026 PFS proposed rule (90 FR 32676), an ACO that is eligible for the health equity adjustment may receive up to a maximum of 10 additional points that are added to its MIPS quality performance category score, the sum of which then becomes the ACO's health equity adjusted quality performance score (87 FR 69831). The application of the health equity adjustment to an ACO's MIPS quality performance category score allows the ACO to achieve a higher quality score that would be used to determine whether the ACO meets the quality performance standard. For performance year 2024 and subsequent performance years, if the ACO's health equity adjusted quality performance score is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, then the ACO is determined to have met the quality performance standard under the Shared Savings Program and is eligible to receive maximum shared savings and avoid maximum shared losses (if applicable), at which point additional ACO quality performance points provide no further benefit.

Another pathway for an ACO to meet the quality performance standard is to meet the criteria for the eCQM/MIPS CQM reporting incentive as described in the CY 2026 PFS proposed rule (90 FR 32676 and 32677). ACOs that meet the criteria for the eCQM/MIPS CQM reporting incentive would meet the

quality performance standard regardless of their MIPS quality performance category score and be eligible to receive maximum shared savings and avoid maximum shared losses, if applicable.

In the CY 2026 PFS proposed rule (90 FR 32677), we stated that, based on performance year 2023 ACO quality results, among 71 ACOs that qualified for the health equity adjustment in performance year 2023, 13 ACOs earned health equity adjustment bonus points with an average of 3.54 bonus points (out of 10) awarded. Since all 13 of the ACOs that received health equity adjustment bonus points also met the criteria for the eCQM/MIPS CQM reporting incentive, these ACOs would have met the quality performance standard to be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable), even if the health equity adjustment bonus points were not applied. This demonstrates the duplicative nature of the health equity adjustment and the eCQM/MIPS CQM reporting incentive. We stated that, although limited data was currently available, we expected that this trend will continue and that ACOs that would have received health equity adjustment bonus points are likely to also meet the criteria for the eCQM/MIPS CQM reporting incentive and meet the quality performance standard in future performance years. The Complex Organization Adjustment upwardly adjusts an ACO's MIPS quality performance category score when the ACO reports eCQMs. As described in the CY 2026 PFS proposed rule (90 FR 32676), an ACO will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340, and the Complex Organization Adjustment may be up to 10 percent of the total available measure achievement points in the quality performance category. Based on the quality measures finalized for the APP Plus quality measure set for the Shared Savings Program (89 FR 98128 through 98130), ACOs that report eCQMs will receive the Complex Organization Adjustment to their MIPS quality performance category score on up to four measures (that is, four points) in performance year 2025, 5 measures (that is, five points) in performance year 2026, and 6 measures (that is, six points) in performance year 2027, if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. In the CY 2026 PFS proposed rule (90 FR 32680), we stated that should we finalize our proposal to remove Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set for performance year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493

Adult Immunization Status, whichever is later, ACOs that report eCQMs would receive the Complex Organization Adjustment on up to seven measures (that is, seven points) if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. [414]As the number of eCQMs that ACOs are required to report in the APP Plus quality set grows, the relative value of the Complex Organization Adjustment will increase. Both the health equity adjustment and the Complex Organization Adjustment serve to upwardly adjust an ACO's quality score to increase the ACO's ability to meet the quality performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring. The health equity adjustment and Complex Organization Adjustment are duplicative because they serve a similar function. The Complex Organization Adjustment is accounted for in the calculation of the ACO's MIPS quality performance category score; whereas, the health equity adjustment bonus points are added to the ACO's MIPS quality performance category score. Both ultimately increase an ACO's MIPS quality performance category score and, therefore, improve the ACO's ability to meet the quality performance standard.

As discussed in the CY 2023 PFS final rule, we finalized the health equity adjustment to support ACOs that report all payer/all patient eCQMs/MIPS CQMs, perform high on quality, and serve a high proportion of underserved beneficiaries (87 FR 69838). We further stated that, because every year a greater proportion of ACOs are making the switch to eCQMs, instituting a health equity adjustment for those ACOs making the switch to eCQMs would allow us to study the impacts and make refinements during subsequent rulemaking (87 FR 69839). Moreover, in the CY 2023 PFS final rule, we expressed our concern that ACOs that serve a large portion of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS may receive lower quality scores during the switch to eCQMs without an adjustment and, in turn, be incentivized to avoid these populations, delay switching to eCQMs for as long as possible, or even cease participation in the Shared Savings Program altogether (87 FR 69839).

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[2]As discussed in section III.F.6.d. of this final rule, we are finalizing the proposal to remove Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set.

As we stated in the CY 2026 PFS proposed rule (90 FR 32678), we believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment sufficiently support ACOs to address the unique challenges they face when reporting all payer/all patient measures and sufficiently support ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS. Both the eCQM/MIPS reporting incentive and the Complex Organization Adjustment have broader applicability than the health equity adjustment. The eCQM/MIPS CQM reporting incentive is available to all ACOs that report eCQMs/MIPS CQMs and meet the criteria for the reporting incentive; whereas the Complex Organization Adjustment is available to all ACOs that report eCQMs and meet the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340 for each eCQM. Due to the criteria that need to be met for an ACO to be eligible to receive the health equity adjustment, it only applies to a select group of ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS. Furthermore, unlike the eCQM/MIPS CQM reporting incentive, the health equity adjustment does not guarantee that ACOs will meet the quality performance standard.

We further stated that we believe the application of the Complex Organization Adjustment and the extension of the eCQM/MIPS CQM reporting incentive, as finalized in prior rules, have made it unnecessary to continue the application of the health equity adjustment to an ACO's quality score. The Complex Organization Adjustment and the extension of the eCQM/MIPS CQM reporting incentive underscore our commitment to all payer/all patient quality measure reporting and are more broadly applicable than the health equity adjustment. Therefore, we proposed to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025. In alignment with the Administration's priority to streamline regulations,[415] our proposal to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 would de-duplicate scoring factors and simplify our quality scoring methodology, without reducing the support available under our policies for ACOs to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

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[415] Refer to Executive Order 14192 "Unleashing Prosperity Through Deregulation" https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation.

Additionally, in the CY 2024 PFS final rule, we finalized that ACOs that report Medicare CQMs would be eligible to have the health equity adjustment added to their quality performance category score when calculating shared savings payments (88 FR 79110). In the CY 2025 PFS final rule, we finalized that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for the measure's first two performance periods in MIPS (89 FR 98120 and 98121). In performance year 2025, all four Medicare CQMs that are in the APP Plus quality measure will be scored using a flat benchmark. In the CY 2026 PFS proposed rule (90 FR 32678), we stated that we believe that the use of flat benchmarks in a measure's first two performance periods in MIPS may allow ACOs with high scores to earn maximum or near maximum measure achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks in a measure's first two performance periods in MIPS also helps to ensure that ACOs with high quality performance on a measure are not penalized as low performers (89 FR 98105). There are scoring scenarios in which ACOs would earn higher measure achievement points under flat benchmarks than they would earn under performance period benchmarks, most notable being scenarios in which ACOs have a tight distribution of performance rates on a measure (89 FR 98119). We stated that we anticipate that flat benchmarks would provide benefits that are duplicative of the health equity adjustment for ACOs reporting Medicare CQMs for performance year 2025, where performance year 2025 is the measure's first or second performance period in MIPS using the Medicare CQM collection type.

In the CY 2026 PFS proposed rule (90 FR 32678 and 32679), we stated that section 1871(e)(1)(A)(ii) of the Act prohibits the Secretary from retroactively applying a substantive change in Medicare regulations unless, as applicable here, the Secretary determines that failure to apply the change retroactively would be contrary to the public interest. We stated that we believed it would be contrary to the public interest to apply the proposed removal of the health equity adjustment applied to an ACO's quality score prospectively only. As such, we proposed to apply the removal retroactively, beginning in performance year 2025. Performance year 2025 will be the first performance year when the Complex Organization Adjustment will apply to ACOs for reporting eCQMs. In performance year 2025, the

eCQM/MIPS CQM reporting incentive will continue to be applicable to ACOs, and all Medicare CQMs in the APP Plus quality measure set will be scored using flat benchmarks.

As we discussed earlier in this section, the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment provide duplicative incentives alongside the incentive provided by the health equity adjustment for ACOs to meet the quality performance standard under the Shared Savings Program. Performance year 2023 ACO quality results demonstrate the duplicative nature of the health equity adjustment and the eCQM/MIPS CQM reporting incentive, where the ACOs that earned health equity adjustment bonus points also met the criteria for the eCQM/MIPS CQM reporting incentive. The health equity adjustment is added to an ACO's MIPS quality performance category score. ACOs that achieve the quality performance standard by meeting the eCQM/MIPS CQM reporting incentive are evaluated on their performance on measure-level quality performance scores, not the ACO's MIPS quality performance category score. As such, health equity adjustment bonus points are not used in the determination of the quality performance standard for ACOs that achieve the quality performance standard by meeting the eCQM/MIPS CQM reporting incentive. This dynamic further adds to the confusion and operational complexity of having multiple duplicative incentives for ACOs to meet the quality performance standard under the Shared Savings Program. Both the health equity adjustment and the Complex Organization Adjustment serve to upwardly adjust an ACO's quality score in order increase the ACO's ability to meet the quality performance standard. Furthermore, we noted earlier in this section that we anticipate that flat benchmarks would provide benefits that are duplicative of the health equity adjustment for ACOs reporting Medicare CQMs for performance year 2025, where performance year 2025 is the measure's first or second performance period in MIPS using the Medicare CQM collection type.

We also discussed that we believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment sufficiently support ACOs to address the unique challenges they face when reporting all payer/all patient measures and sufficiently support ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS (these are the goals of the health equity adjustment) due to the broader applicability of both the eCQM/MIPS reporting incentive and the Complex Organization Adjustment than the health equity adjustment.

We stated that we believe that it is in the public interest to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 to simplify our quality scoring methodology for ACOs, while maintaining sufficient support for ACOs to meet the quality performance standard through the application of the eCQM/MIPS CQM reporting incentive, the Complex Organization Adjustment, and use of flat benchmarks for Medicare CQMs. We noted that our proposal would allow ACOs to focus on a simpler scoring methodology that includes more widely applicable incentives, determine how to improve the quality of care furnished to their beneficiaries, and operate with greater focus to improve care coordination activities, thus resulting in the improvement of their performance on quality measures and ability to serve their beneficiaries. We further stated that making this change retroactively would provide greater clarity for ACOs by establishing continuity in resource language between performance year 2025 and subsequent performance years, allowing ACOs to plan ahead and have additional time to update internal operations and more easily prepare for consistent quality performance standards.

Specifically, we proposed to revise and republish § 425.512(b), to include the following proposed amendments:

- At § 425.512 removing paragraph (b)(3).
- At § 425.512 redesignating paragraphs (b)(4) and (b)(5) as paragraphs (b)(3) and (b)(4), respectively.
- Revising references to paragraphs (b)(4) and (b)(5) (which we proposed to redesignate as paragraphs (b)(3) and (b)(4)), as follows:

++ At § 425.512 in paragraphs (b)(1) and (b)(2), removing the reference "paragraph (b)(4)" and adding in its place the reference "paragraph (b)(3)".

++ At § 425.512 in paragraph (b)(4)(iii) (which we proposed to redesignate as paragraph (b)(3)(iii)), removing the reference "paragraph (b)(4)(ii)" and adding in its place the reference "paragraph (b)(3)(ii)".

++ At § 425.512 in paragraph (b)(4)(iv)(A)(*2*) (which we proposed to redesignate as paragraph (b)(3)(iv)(A)(*2*)) introductory text, removing the reference "paragraph (b)(4)(iv)(A)(*1*)(*ii*)" and adding in its place the reference "paragraph (b)(3)(iv)(A)(*1*)(*ii*)".

++ At § 425.512 in paragraph (b)(4)(iv)(B) (which we proposed to redesignate as paragraph (b)(3)(iv)(B)), removing the reference "paragraph (b)(4)(iv)(A)" and adding in its place the reference "paragraph (b)(3)(iv)(A)".

++ At § 425.512 in paragraph (b)(4)(v) (which we proposed to redesignate as paragraph (b)(3)(v)), removing the references to "paragraph (b)(4)(iv)(B)", "paragraph (b)(4)(iii)", and "paragraph (b)(4)(iv)" and adding in their place the references to "paragraph (b)(3)(iv)(B)", "paragraph (b)(3)(iii)", and "paragraph (b)(3)(iv)", respectively.

- At § 425.512 in paragraph (b)(4)(iv)(A)(*2*)(*ii*) (which we proposed to redesignate as paragraph (b)(3)(iv)(A)(*2*)(*ii*)), removing the phrase "For performance year 2024 and subsequent performance years" and adding in its place the phrase "For performance year 2024".

- At § 425.512 in paragraph (b)(5) (which we proposed to redesignate as paragraph (b)(4)), revising the introductory text and paragraph references to read as follows: "Use of ACO's quality score. The ACO's quality score, determined in accordance with paragraphs (b)(1) through (3) of this section, is used as follows:".

Since the publication of the CY 2026 PFS proposed rule, the performance year 2024 ACO quality results have become available. We used this data to conduct simulations on how the proposed removal of the health equity adjustment and the application of the eCQM/MIPS CQM reporting incentive, Complex Organization Adjustment, and flat benchmarking policies for Medicare CQMs would impact ACOs' quality scores. Based on this analysis described in further detail below, we continue to believe that the health equity adjustment would be duplicative with other adjustments in the quality scoring methodology and its proposed removal would not reduce the support available under our policies for ACOs to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

To inform the results of these simulations, we note that there are three pathways through which an ACO can meet the Shared Savings Program quality performance standard in performance year 2024. Meeting any one of these three pathways allows ACOs to be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable). These pathways are: (1) achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS quality

performance category scores, excluding entities/providers eligible for facility-based scoring as described at § 425.512(a)(5)(i)(A)(*1*); (2) meeting the criteria for the eCQM/MIPS CQM reporting incentive as described at § 425.512(a)(5)(i)(A)(*2*); or (3) meeting the criteria for ACOs in the first performance year of their first agreement period as described at § 425.512(a)(2)(ii). ACOs can also meet the quality performance standard if they qualify for the Shared Savings Program's quality extreme and uncontrollable circumstances (EUC) policy described at § 425.512(c). We further clarify that, unlike receiving the eCQM/MIPS CQM reporting incentive, receiving the health equity adjustment does not equate to meeting the Shared Saving Program's quality performance standard; instead, it provides bonus points to eligible ACOs that are added to their quality score. The sum of these bonus points and the ACO's MIPS quality performance category score is then used to determine whether the ACO achieved a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring and thus whether or not the ACO met the quality performance standard under the first pathway described above.

Overview of performance year 2024 quality results and simulations: Based on performance year 2024 ACO quality results, 39 ACOs earned health equity adjustment bonus points with an average of 4 bonus points (out of 10) awarded. Out of 39 ACOs that earned health equity adjustment bonus points for performance year 2024:

- In total, 26 out of 39 ACOs that earned health equity adjustment bonus points were eligible for the eCQM/MIPS CQM reporting incentive because they reported either eCQMs or MIPS CQMs and met the criteria for the eCQM/MIPS reporting incentive.

++ Additionally, 8 ACOs among the 26 ACOs that received the eCQM/MIPS CQM reporting incentive and met the quality performance standard as a result reported MIPS CQMs. We note that because these 8 ACOs did not report eCQMs, they would not have been eligible to receive the Complex Organization Adjustment if it was applicable in performance year 2024.

++ 18 ACOs among the 26 ACOs that received the eCQM/MIPS CQM reporting incentive reported eCQMs and would have been awarded additional measure achievement points added to their MIPS quality performance category score under the Complex Organization Adjustment if it was applicable in

performance year 2024; these ACOs also met the criteria for the eCQM/MIPS CQM reporting incentive and the quality performance standard as a result.

- 13 ACOs reported only Medicare CQMs, and as a result, they would not have been eligible for the eCQM/MIPS CQM reporting incentive or Complex Organization Adjustment. Starting in performance year 2025, Medicare CQMs will be scored using flat benchmarks for their first two performance periods in MIPS as described at § 414.1380(b)(1)(ii)(F). These 13 ACOs would have been eligible to have the three Medicare CQMs they reported scored using flat benchmarks if the flat benchmarks for Medicare CQMs policy were applicable in performance year 2024.

eCQM/MIPS CQM Reporting Incentive: Out of these 39 ACOs, 26 ACOs reported eCQMs/MIPS CQMs and met the quality performance standard by meeting the criteria for the eCQM/MIPS CQM reporting incentive, through which they were eligible to receive maximum shared savings and avoid maximum shared losses (if applicable) regardless of their quality score. These 26 ACOs did not receive any further benefit from earning health equity adjustment bonus points, thus demonstrating the duplicative nature of the health equity adjustment and the eCQM/MIPS CQM reporting incentive to achieve the quality performance standard based on both performance year 2023 (as described in the CY 2026 PFS proposed rule (90 FR 32677)) and 2024 ACO quality results.

Use of flat benchmarks to score Medicare CQMs: In performance year 2024, there were 13 ACOs that earned health equity adjustment bonus points and reported only Medicare CQMs; therefore, these ACOs were not eligible for the eCQM/MIPS CQM reporting incentive. Even though these ACOs earned health equity adjustment bonus points, the bonus points were insufficient in helping the ACOs meet one pathway to the quality performance standard, which is based on achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring; however, these 13 ACOs were able to meet the quality performance standard after the application of the policy for ACOs in the first performance year of their first agreement period as described at § 425.512(a)(2) or the quality EUC policy as described at § 425.512(c).

We conducted an internal analysis of the performance year 2024 ACO quality results to better understand the potential impact of the proposed removal of the health equity adjustment on these ACOs.

Specifically, we simulated the application of flat benchmarks for Medicare CQMs (as described at § 414.1380(b)(1)(ii)(F)), which will be in effect starting in performance year 2025. Had flat benchmarks been applied to the three Medicare CQMs in the APP quality measure set in performance year 2024, the average MIPS quality performance category score earned by these 13 ACOs would have been on average 14 percentage points higher compared to an average increase of 4 percentage points that these ACOs earned from the health equity adjustment in performance year 2024, a difference of 10 percentage points. This would thus increase the likelihood that these ACOs would meet the quality performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring or the alternative quality performance standard. Additionally, when we reviewed the number of percentage points each of the 13 ACOs would have received under flat benchmarks as compared to the number of percentage points received through the health equity adjustment, we found that all 13 of these ACOs would have received a greater percentage point increase from flat benchmarks for Medicare CQMs than what they had received under the health equity adjustment. As such, we anticipate that, while ACOs that choose to report Medicare CQMs would not be eligible for the eCQM/MIPS reporting incentive or the Complex Organization Adjustment, these ACOs would likely sufficiently benefit from our policy to score Medicare CQMs using flat benchmarks as described at § 414.1380(b)(1)(ii)(F). Specifically, we anticipate that these ACOs would receive a positive scoring impact under flat benchmarks for Medicare CQMs, that would be greater than the current positive scoring impact these ACOs received under the health equity adjustment.

Complex Organization Adjustment: We simulated the impact that the Complex Organization Adjustment, which is effective beginning in the CY 2025 performance period/2027 MIPS payment year as described at § 414.1380(b)(1)(vii)(C), would have had on the 39 ACOs that earned health equity adjustment bonus points if it had been applied in performance year 2024. We found that out of the 26 ACOs that earned health equity adjustment bonus points in performance year 2024 and reported eCQMs/MIPS CQMs, 18 ACOs would have been eligible to receive the Complex Organization Adjustment because these ACOs submitted at least one eCQM. Had the Complex Organization Adjustment been applied in performance year 2024, the average MIPS quality performance category

score for these 18 ACOs would have been 6 percentage points on average as compared to an average increase of 3 percentage points that these ACOs earned through the application of the health equity adjustment bonus points, thus increasing the likelihood that these ACOs would meet the quality performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring. The other eight ACOs reported MIPS CQMs and not eCQMs and thus would not have been eligible to receive the Complex Organization Adjustment. We also note that all 26 ACOs that reported eCQMs/MIPS CQMs (that is, the 18 the ACOs that would have been eligible for the Complex Organization Adjustment had it been applicable for performance year 2024 and the eight ACOs that did not submit at least one eCQM and would not have been eligible for the Complex Organization Adjustment had it been applicable for performance year 2024) were eligible for the eCQM/MIPS CQM reporting incentive, which allowed these ACOs to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable) regardless of their quality score.

We received public comments on the proposals related to removing the health equity adjustment applied to an ACO's quality score beginning in performance year 2025. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to remove the health equity adjustment applied to an ACO's quality score. These commenters supported the goal of simplifying the scoring methodology and providing incentives like the Complex Organization Adjustment and believed a clear and streamlined approach to quality scoring allows ACOs to focus more on care improvement activities over complex reporting mechanics.

Response: We thank commenters for their support of our proposal.

Comment: Many commenters disagreed that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment are duplicative of the health equity adjustment and stated that they serve different purposes. The commenters noted that these adjustments are not uniformly applied across ACOs and vary based on reporting pathways. A commenter stated that these incentives, while valuable for encouraging certain types of data reporting, do not provide a sufficiently broad or comprehensive

support mechanism for essential hospitals to thrive in a value-based care environment. Another commenter questioned why the health equity adjustment was added to begin with if it was duplicative with other adjustments. Many commenters recommended that we retain the health equity adjustment applied to an ACO's quality score.

Response: In response to comments stating that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment are not uniformly applied across ACOs and vary based on reporting pathways, we note that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment are available to all ACOs based on the reporting option ACOs choose. In contrast, the health equity adjustment eligibility criteria limit the adjustment's applicability to a select group of ACOs based on the proportion of assigned beneficiaries who are dually eligible for Medicare and Medicaid and the Medicare Part D LIS. Furthermore, unlike the eCQM/MIPS CQM reporting incentive, the health equity adjustment does not guarantee that ACOs will meet the quality performance standard.

We believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment sufficiently support ACOs to address the unique challenges they face when reporting all payer/all patient measures and sufficiently support ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS, including essential hospitals. Based on our analysis of performance year 2024 ACO quality results as described above and as discussed in our responses below, we continue to believe that the health equity adjustment is duplicative of the eCQM/MIPS CQM reporting incentive and Complex Organization Adjustment.

In response to the comment that questioned why the health equity adjustment was added to begin with if it was duplicative of other adjustments, we note that, as discussed in the CY 2023 PFS final rule, our aim in finalizing the health equity adjustment was to encourage high ACO quality performance, reinforce ACOs' transition to reporting all payer/all patient eCQMs/MIPS CQMs, and provide an incentive for ACOs to provide high quality care to all of the populations they serve (87 FR 69839). We also stated that, because every year a greater proportion of ACOs are making the switch to eCQMs, instituting a health equity adjustment for those ACOs making the switch to eCQMs will allow us to study the impacts and make refinements during subsequent rulemaking (87 FR 69839). Since we adopted the

health equity adjustment, we also note that we have added or extended other incentives to reinforce ACOs' transition to reporting eCQMs/MIPS CQMs, including making the Complex Organization Adjustment available to ACOs that report eCQMs, extending the eCQM/MIPS CQM reporting incentive, and applying flat benchmarks to Medicare CQMs in their first two performance periods in MIPS.

Comment: We received several comments addressing whether the eCQM/MIPS CQM reporting incentive was duplicative of the health equity adjustment. A commenter suggested CMS acquire additional data to determine if the eCQM/MIPS CQM reporting incentive and the health equity adjustment are duplicative. A commenter stated that, even though CMS referenced that all 13 of the ACOs that received the health equity adjustment bonus points in performance year 2023 also met the criteria for the eCQM/MIPS CQM reporting incentive, performing well in underserved areas does not necessarily mean that an ACO will meet the standard for the eCQM/MIPS CQM reporting incentive. The commenter noted that maintaining the health equity adjustment alongside the eCQM/MIPS CQM reporting incentive would continue to appropriately reward providers who consider all aspects of a patient's health. A commenter stated that the eCQM/MIPS CQM reporting incentive is not duplicative of the health equity adjustment because the former rewards ACOs for their reporting method while the latter rewards ACOs due to population-based challenges.

Response: As described in the CY 2026 PFS proposed rule (90 FR 32676), an ACO that is eligible for the health equity adjustment may receive up to a maximum of 10 additional points that are added to its MIPS quality performance category score, the sum of which then becomes the ACO's health equity adjusted quality performance score. The application of the health equity adjustment to an ACO's MIPS quality performance category score allows the ACO to achieve a higher quality score that would be used to determine whether the ACO meets the quality performance standard. We finalized in the CY 2023 PFS final rule (87 FR 69842) and the CY 2024 final rule (88 FR 79109 and 79110) that, for performance year 2024 and subsequent performance years, if the ACO's health equity adjusted quality performance score was equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, then the ACO was determined to have met the quality performance standard under the Shared Savings Program and was eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

Another pathway for an ACO to meet the quality performance standard is to meet the criteria for the eCQM/MIPS CQM reporting incentive as described in the CY 2026 PFS proposed rule (90 FR 32676 and 32677). ACOs that meet the criteria for the eCQM/MIPS CQM reporting incentive would meet the quality performance standard regardless of what their MIPS quality performance category score is and be eligible to receive maximum shared savings and avoid maximum shared losses, if applicable. ACOs that achieve the quality performance standard by meeting the eCQM/MIPS CQM reporting incentive are evaluated on their performance on measure-level quality performance scores, not the ACO's MIPS quality performance category score. As such, health equity adjustment bonus points are not used in the determination of the quality performance standard for ACOs that achieve the quality performance standard by meeting the eCQM/MIPS CQM reporting incentive.

In response to comments that suggested CMS acquire more data before determining whether the eCQM/MIPS CQM reporting incentive is duplicative with the health equity adjustment, we discussed earlier in this section of the final rule that performance year 2024 ACO quality results have become available since the publication of the CY 2026 PFS proposed rule. We found that all 26 ACOs that earned health equity adjustment bonus points and reported eCQMs/MIPS CQMs also met the criteria for the eCQM/MIPS CQM reporting incentive and thus meeting the quality performance standard and demonstrating the duplicative nature of the health equity adjustment and the eCQM/MIPS CQM reporting incentive.

Based on our experience with the program and our knowledge of the ACOs that participate in it, we expect that this trend will continue and that ACOs that would have received health equity adjustment bonus points will continue to benefit from the eCQM/MIPS CQM reporting incentive.

Comment: We received comments specifically addressing whether the Complex Organization Adjustment was duplicative of the health equity adjustment. A commenter stated that the health equity adjustment complements rather than duplicates the Complex Organization Adjustment. Another commenter stated that the Complex Organization Adjustment is tied to eCQM reporting but fails to capture the full spectrum of challenges that essential hospitals encounter. A commenter stated that the Complex Organization Adjustment and the health equity adjustment are not duplicative because the former addresses workflow burden and the latter accounts for unique circumstances faced by ACOs that

serve a high proportion of beneficiaries who are from underserved neighborhoods, eligible for the Medicare Part D LIS, or dual eligibles. The commenter stated that many of these ACOs do not have the capability to report eCQMs in the near term and thus cannot qualify for the Complex Organization Adjustment. Another commenter stated that the health equity adjustment and the Complex Organization Adjustment capture two different areas of work and incorrectly noted that less than one-fifth (13/71) of ACOs who received the health equity adjustment also received the Complex Organization Adjustment. The commenter stated that the Complex Organization Adjustment accounts for organizational complexities encountered with APMs, while the health equity adjustment is intended to account for low-income beneficiaries who may have poorer health outcomes and higher resource needs. A commenter urged CMS to retain the Complex Organization Adjustment and the health equity adjustment on a permanent basis because the Complex Organization Adjustment was intended to provide incentives for the financial and technological difficulties ACOs face as they transition to all payer/all patient reporting via eCQMs and achieve data completeness thresholds. Some commenters proposed an alternative to removing the health equity adjustment where an ACO can choose either the Complex Organization Adjustment or the health equity adjustment. A commenter stated that CMS should increase the Complex Organization Adjustment maximum to 10 points if the health equity adjustment is removed.

Response: In response to the comment that stated that the Complex Organization Adjustment does not capture the full spectrum of challenges encountered by essential hospitals, we note that both the health equity adjustment and the Complex Organization Adjustment upwardly adjust an ACO's MIPS quality performance category score to increase the ACO's ability to meet the quality performance standard, but do not guarantee that the ACO will meet the quality performance standard. Specifically, the Complex Organization Adjustment upwardly adjusts an ACO's MIPS quality performance category score by adding points to specific measures where the ACO reported via the eCQM collection type and met the case minimum and data completeness requirements; whereas, the health equity adjustment bonus points are added to the ACO's overall MIPS quality performance category score, which is used to determine the ACO's quality score for the Shared Savings Program. As described in the CY 2026 PFS proposed rule (90 FR 32676), an ACO will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at §

414.1340, and the Complex Organization Adjustment may be up to 10 percent of the total available measure achievement points in the quality performance category. Based on the quality measures finalized for the APP Plus quality measure set that Shared Savings Program ACOs are required to report beginning in performance year 2025 (89 FR 98128 through 98130), ACOs that report eCQMs will receive the Complex Organization Adjustment to their MIPS quality performance category score on up to four measures (that is, four points) in performance year 2025, 5 measures (that is, 5 points) in performance year 2026, and 6 measures (that is, 6 points) in performance year 2027, if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. We are finalizing our proposal to remove Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in section III.F.6.d. of this final rule; therefore, for performance year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493 Adult Immunization Status, whichever is later, ACOs that report eCQMs would receive the Complex Organization Adjustment on up to seven measures (that is, seven points) if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340.

We disagree with the commenter's suggestion that CMS increase the Complex Organization Adjustment's maximum value to 10 points. As we stated in the CY 2025 PFS final rule, in limiting the application to virtual groups and APM Entities and capping the adjustment to 10 percent of the total achievable points in the quality performance category, the Complex Organization Adjustment will serve to help these participants overcome barriers to eCQM reporting while reducing scoring inflation (89 FR 98438).

As discussed earlier in this section of the final rule, we conducted an internal analysis of performance year 2024 ACO quality results where we simulated the impact of the Complex Organization Adjustment if it had been applied in performance year 2024. We found that for the 18 ACOs that would have been eligible to receive the Complex Organization Adjustment, the average MIPS quality performance category score would have been 6 percentage points higher on average as compared to an average increase of 3 percentage points that these ACOs earned through the application of the health equity adjustment bonus points, thus increasing the likelihood for these ACOs to meet the quality

performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring. Based on our experience with the program and knowledge of the ACOs that participate in it, we expect that estimated impacts will continue and that ACOs reporting eCQMs that would have received health equity adjustment bonus points are poised to have net benefits from the Complex Organization Adjustment.

In response to the comment that stated that the Complex Organization Adjustment does not account for unique circumstances faced by ACOs that serve a high proportion of beneficiaries, we note that, while the methodology for the health equity adjustment and the Complex Organization Adjustment differ, both adjustments aim to upwardly adjust an ACO's quality score for purposes of determining whether an ACO met quality performance standard. The Complex Organization Adjustment was finalized to support full and equitable participation in all payer/all patient collection types, especially among large groups such as Shared Savings Program ACOs (89 FR 98102). The overlap in fundamental goals between the Complex Organization Adjustment and health equity adjustment demonstrates how the former will provide continued support for ACOs.

In response to the comment that many ACOs do not have the capability to report eCQMs in the near term and thus cannot qualify for the Complex Organization Adjustment, we note that these ACOs have the option to report Medicare CQMs, and as such, would benefit from the flat benchmark for Medicare CQM policy described at § 414.1380(b)(1)(ii)(F). As discussed earlier in this section of the final rule, based on an internal simulation of performance year 2024 ACO quality results, the 13 ACOs that earned health equity adjustment bonus points in performance year 2024 and reported Medicare CQMs would have benefited from the flat benchmarks for Medicare CQMs to a greater degree than the health equity adjustment, had that policy been applicable in performance 2024.

We disagree with the suggestion for ACOs to choose to have the health equity adjustment or Complex Organization Adjustment applied to the ACOs' MIPS quality performance category score. As discussed in this section of the final rule, our simulated analysis suggests that ACOs are expected to have a greater increase in their MIPS quality performance category scores due to the Complex Organization Adjustment as compared to the health equity adjustment.

Comment: A commenter stated that retaining the health equity adjustment is ideal as other incentives begin to be phased out as eCQMs become the standard. A commenter stated that the end of the eCQM/MIPS CQM reporting incentive after performance year 2026 makes it a temporary replacement for the health equity adjustment.

Response: We disagree with the commenter. We clarify that, as stated in the CY 2026 PFS proposed rule (90 FR 32676), we further extended the eCQM/MIPS CQM reporting incentive in the CY 2025 PFS final rule (89 FR 98124) to continue to support ACOs in the transition to eCQMs for digital quality measurement reporting.

Specifically, for performance year 2025 and subsequent performance years for ACOs reporting eCQMs, and performance years 2025 and 2026 for ACOs reporting MIPS CQMs, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the MIPS data completeness requirement for all eCQMs/MIPS CQMs;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set; and
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set (89 FR 98122 through 98124).

Comment: Several commenters stated that reporting eCQMs is not feasible despite the incentives, due to technology constraints and vendors' abilities to accurately aggregate and deduplicate data across numerous disparate EHRs and other data sources. The commenters further noted that this transition can be particularly challenging for smaller, less well-resourced organizations. The commenters further noted that removal of the health equity adjustment may result in these organizations losing out on earned shared savings, thus being left with fewer resources to fund the reporting transition.

Response: Regarding concern over vendors' abilities to accurately aggregate and deduplicate data across numerous disparate EHRs and other data sources, we note that in the CY 2025 PFS final rule, we

directed readers to guidance on reporting eCQMs/MIPS CQMs that recognized these challenges (89 FR 98108). Specifically, for concerns related to de-duplication, we encouraged ACOs and their vendors to consider using our DedupliFHIR open-source data deduplication and record matching tool. The tool includes a backend library and a front-end desktop application that can be downloaded from the DedupliFHIR GitHub repository at https://github.com/DSACMS/dedupliFHIR. We continue to encourage ACOs and their vendors to participate in our regular QCDR and Qualified Registry support calls and to submit questions to the Quality Payment Program help desk, as needed. Additionally, for ACOs with significant EHR vendor concerns, when issues of potential noncompliance with certification requirements are unresolvable, we note that the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) has provided a complaint process for certified products available to the public at https://www.healthit.gov/topic/certified-health-it-complaint-process.

In our responses above, we describe why we continue to believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment provide duplicative incentives to the incentive provided by the health equity adjustment, for ACOs to meet the quality performance standard under the Shared Savings Program and be eligible to receive maximum shared savings and avoid maximum shared losses, if applicable. Thus, we disagree with commenters that the removal of the health equity adjustment will result in these organizations losing out on shared savings. As discussed earlier in this section of the final rule, there were 13 ACOs that earned health equity adjustment bonus points in performance year 2024 and reported Medicare CQMs. When we simulated the application of flat benchmarks for Medicare CQMs on the performance year 2024 ACO quality results for these 13 ACOs, we found that they scored higher on average when scored with flat benchmarks compared to when their scores were adjusted by the health equity adjustment. The average MIPS quality performance category score earned by these 13 ACOs would have been 14 percentage points higher compared to an average increase of 4 percentage points that these ACOs earned from the health equity adjustment in performance year 2024, a difference of 10 percentage points; therefore, increasing the likelihood for these ACOs to meet the quality performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible

for facility-based scoring.

Comment: Many commenters stated that the removal of the health equity adjustment would disproportionately harm ACOs serving beneficiaries who are dually eligible for Medicare and Medicaid and other complex populations. The commenters noted that the adjustment provides a critical guardrail for organizations with complex beneficiary populations, including high proportions of dual eligible populations. A commenter further noted that despite providing high quality care, due to high exclusion rates and other measure-related challenges, ACOs serving these populations often have lower quality scores and that this change jeopardizes the shared savings of organizations serving some of the most high-cost and vulnerable Medicare beneficiaries. A commenter stated, as an example, that FQHCs' beneficiaries are predominantly dual eligible or Medicare Part D LIS eligible, and the health equity adjustment recognizes the additional effort required to improve outcomes for these populations.

Response: We acknowledge commenters' concerns. In the CY 2026 PFS proposed rule (90 FR 32678), we stated that we believe that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment sufficiently support ACOs to address the unique challenges they face when reporting all payer/all patient measures and support ACOs that serve large proportions of beneficiaries dually eligible for Medicare and Medicaid and the Medicare Part D LIS. Both the eCQM/MIPS reporting incentive and the Complex Organization Adjustment have broader applicability than the health equity adjustment. The eCQM/MIPS CQM reporting incentive is available to all ACOs that report eCQMs/MIPS CQMs and meet the criteria for the reporting incentive; whereas, the Complex Organization Adjustment is available to all ACOs that report eCQMs and meet the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340 for each eCQM. The criteria to receive the health equity adjustment is limited to ACOs with a certain proportion of assigned beneficiaries who are dually eligible for Medicare and Medicaid or receive Medicare Part D LIS. Furthermore, unlike the eCQM/MIPS CQM reporting incentive, the health equity adjustment does not guarantee that ACOs will meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable). Our analyses detailed above illustrate the support that could be provided by other incentives and demonstrate that the health equity adjustment is otherwise duplicative of these other incentives. The 13 ACOs that received the health equity adjustment

that reported Medicare CQMs were not eligible for the eCQM/MIPS CQM reporting incentive, and none of those 13 ACOS would have met the quality performance standard with the health equity adjustment. As noted above, flat benchmarks would have provided a greater benefit and increased the chance for these ACOs that reported Medicare CQMs to meet the quality performance standard.

Comment: A commenter stated that removal of the health equity adjustment would have detrimental effects on patients' health and therefore lead to higher costs. Additionally, several commenters noted that ACOs tend to contribute some of the highest savings to the Medicare Trust Funds on a per-beneficiary basis. These commenters noted that eliminating the health equity adjustment will drive out organizations CMS seeks to retain.

Response: We disagree with commenters that the removal of the health equity adjustment will lead to higher costs. Our analyses show that there are other adjustments that support ACOs in quality reporting. We believe specifically the eCQM/MIPS CQM reporting incentive and Complex Organization Adjustment, as well as flat benchmarks under Medicare CQM reporting are sufficient incentives to retain participation of ACOs so they can continue to coordinate care and achieve savings to Medicare.

Comment: A few commenters stated that, absent the adjustment, ACOs with higher amounts of Medicaid patients will likely perform worse on all-payer measures, which effectively turns quality measurement into a measure of an ACO's population mix rather than quality performance.

Response: As discussed in section III.F.8.(2) of this final rule, the health equity benchmark adjustment (HEBA) that we are finalizing to rename the "population adjustment" modifies an ACO's historical benchmark according to the proportion of its assigned beneficiaries who are dually eligible for Medicare and Medicaid or receive the Medicare Part D LIS. We note that the population adjustment that went into effect starting in performance year 2025 will continue to provide ACOs with additional financial resources to serve dual eligible beneficiaries and beneficiaries who receive the Medicare Part D LIS since it is intended to encourage ACOs to attract and retain medically complex beneficiaries. We further believe that the population adjustment will continue to offer a targeted mechanism to support ACO participants such as hospitals and FQHCs that care for a high proportion of dual eligible or Medicare Part D LIS eligible beneficiaries.

Comment: The commenters noted that the ACO's ability to change its participation list might

mean that it drops practitioners that are less "efficient" compared to their region or are serving an increasing number of Medicaid patients.

Response: Regarding commenters' concerns related to ACOs modifying their participant list to exclude "efficient" practitioners, we do not believe that the removal of the health equity adjustment will prompt the removal of practitioners from ACO participant lists because we believe the population adjustment to the historical benchmark provides adequate incentive for ACOs not to engage in this behavior.

Comment: A commenter stated that the health equity adjustment ensures that the Medicare payment methodology accounts for the complexity of higher-risk populations. Another commenter stated that removing the adjustment would eliminate a crucial mechanism designed to reward and incentivize clinicians who provide care to underserved and at-risk populations. The commenter believed that the health equity adjustment is essential to ensure that ACOs treating marginalized communities are supported and can help bolster ACOs' ability to earn shared savings.

A commenter stated that removing the health equity adjustment will likely disincentivize ACOs from forming in areas with greater proportions of populations with unmet social and economic need and incentivize ACOs to exclude providers who primarily serve these populations. Another commenter stated that removal of the health equity adjustment should be reconsidered because it aligns with the goal of providing specific populations with more coordinated and cost-effective care.

Response: We disagree with the comments that the proposed removal of the health equity adjustment would disincentivize ACOs from participating and serving higher-risk populations. As we described in the CY 2026 PFS proposed rule (90 FR 32677 through 32679), we continue to believe the health equity adjustment is duplicative with other adjustments in the quality scoring methodology. Removing the health equity adjustment is balanced with the availability of other adjustments to support ACOs, including the eCQM/MIPS CQM reporting incentive, Complex Organization Adjustment and flat benchmarks for Medicare CQMs. Additionally, the removal of the health equity adjustment will help to simplify the quality scoring methodology.

Comment: A commenter stated that maintaining this adjustment could help CMS retain data on providers and populations with risk factors impacting delivery of care, which could inform future decision making.

Response: Removal of the health equity adjustment does not mean that we would lose the data on provider and ACO assigned beneficiary characteristics used to calculate and implement the health equity adjustment. We would continue to have access to information such as ACO assigned beneficiaries that are dually eligible for Medicare and Medicaid or receive the Medicare Part D LIS since we maintain this data for other policies and programs. This data could be used to inform future analyses if needed.

Comment: A commenter stated that the removal of the health equity adjustment would lower the final MIPS scores of ACO providers in MIPS APM tracks of the Shared Savings Program, and therefore, lower their MIPS payment adjustment and financially harm providers.

Response: We believe that the commenter misunderstood how the health equity adjustment is applied under the Shared Savings Program. The health equity adjustment bonus points are added to the ACO's MIPS quality performance category score for purposes of calculating the ACO's quality score under the Shared Savings Program only. The health equity adjustment is not applied to an ACO's MIPS quality performance category score for purposes of calculating the ACO's MIPS final scores or MIPS payment adjustment. As such, removal of the health equity adjustment would not impact an ACO's performance under MIPS.

Comment: A commenter stated that the health equity adjustment should be retained because it is available to ACOs that report Medicare CQMs, unlike the eCQM/MIPS CQM reporting incentive and Complex Organization Adjustment. Another commenter proposed an alternative for CMS to update the health equity adjustment to only apply to ACOs that report via Medicare CQMs to eliminate the overlap between these adjustments. Another commenter stated that removing financial resources to Medicare CQM reporters potentially decreases participation in the program, contrary to CMS' goal of having all patients in an accountable care relationship by 2030. Another commenter stated that flat benchmarks for Medicare CQM and the health equity adjustment are not duplicative because the former is uniformly applied and does not account for the worse health outcomes consistently observed in underserved populations. The commenter further stated that flat benchmarks are temporary and are not a lasting offset

to the unique challenges faced by ACOs that serve high ADI, Medicare Part D LIS, and dual eligible populations.

Response: The option to report using the eCQM/MIPS CQM/Medicare CQM collection types in performance year 2026 and the eCQM/Medicare CQM in performance year 2027 and subsequent years, will allow ACOs to select the submission method that is most appropriate and advantageous for their situation and technological capabilities. We note that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment are available to ACOs that choose to report via the eCQM or MIPS CQM collection type, or the eCQM collection type, respectively. ACOs that choose to report the Medicare CQM collection type will benefit from the flat benchmark for Medicare CQMs policy described at § 414.1380(b)(1)(ii)(F).

In response to the comment that stated that flat benchmarks for Medicare CQMs and the health equity adjustment are not duplicative because the former is uniformly applied and does not account for the worse health outcomes consistently observed in underserved populations, we note that while the methodology for the application of the health equity adjustment and flat benchmarks for Medicare CQMs differ, as discussed in the CY 2026 PFS proposed rule (90 FR 32678), the use of flat benchmarks in a Medicare CQM measure's first two performance periods in MIPS may allow ACOs with high scores to earn maximum or near maximum measure achievement points while allowing for room for quality improvement and rewarding that improvement in subsequent years and to help ensure that ACOs with high quality performance on a measure are not penalized as low performers. Similar to the health equity adjustment, flat benchmarks for Medicare CQMs are applicable to the Medicare CQMs included in the APP Plus quality measure set. Specifically, as discussed in the CY 2025 PFS final rule, Medicare CQM measures are eligible for flat benchmarks from performance year 2025 to performance year 2028 (89 FR 98121). The following measures are included:

- Medicare CQM version of Quality ID: 112 Breast Cancer Screening will be scored using a flat benchmark in performance years 2025 and 2026.
- Medicare CQM version of Quality ID: 113: Colorectal Cancer Screening and Quality will be scored using flat benchmarks in performance years 2026 and 2027.
- Medicare CQM version of Quality ID: 305 Initiation and Engagement of Substance Use

Disorder Treatment will be scored using a flat benchmark in performance year 2027 and 2028.

- Medicare CQM version of Quality ID: 493 Adult Immunization Status will be eligible for flat benchmarks for two years beginning with performance year 2028 or the performance year that is one year after the eCQM specifications become available for these measures, whichever is later.

We also note that, while our policy for flat benchmarks for Medicare CQMs described at § 414.1380(b)(1)(ii)(F) is only applicable to measures during their first two performance periods in MIPS, as discussed in the CY 2025 PFS final rule, the use of historical benchmarks, when data are available after the first two performance periods in MIPS, will allow ACOs to know the benchmarks prior to the start of the performance year and create opportunities for improvement (89 FR 98120). We further note that we will monitor ACOs' uptake of eCQMs and Medicare CQMs and should we consider extending flat benchmarks for Medicare CQMs, we would do so through notice and comment rulemaking.

In response to the comment that stated that removing financial resources to Medicare CQM reporters potentially decreases participation in the program, we refer interested parties to the discussion of an internal simulation of performance year 2024 ACO quality results found earlier in this section of the final rule. Specifically, we simulated the application of flat benchmarks for Medicare CQMs for the 13 ACOs that earned health equity bonus points and reported Medicare CQMs in performance year 2024. Had flat benchmarks been applied to the three Medicare CQMs in the APP quality measure set in performance year 2024, the average MIPS quality performance category score earned by these 13 ACOs would have received an average increase of 14 percentage points higher compared to an average increase of 4 percentage points that these ACOs earned from the health equity adjustment in performance year 2024, a difference of 10 percentage points. Additionally, we note that all 13 of these ACOs would have received a greater percentage point increase from flat benchmarks for Medicare CQMs than what they had received under the health equity adjustment. Based on these results, we believe that flat benchmarks for Medicare CQMs will support ACOs in meeting the quality performance standard and alternative quality performance standard in a manner that is equal to or greater than the benefit ACOs received from the health equity adjustment. Moreover, the collective benefit of flat benchmarks for Medicare CQMs, in conjunction with the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment, would provide sufficient support to ACOs to substantiate the sunsetting of the health equity adjustment.

For the reasons described in this section of the final rule and the results noted previously, we also disagree with the comment that proposed an alternative for CMS to update the health equity adjustment to only apply to ACOs that report via Medicare CQMs to eliminate the overlap between these adjustments.

Comment: A commenter noted that the expansion of the APP Plus quality measure set is not duplicative of the health equity adjustment because these measures are domains where dual eligible and rural populations historically perform worse due to systemic barriers and noted that adding more of these measures will increase disparities and heighten the need for the health equity adjustment.

Response: We did not state in the CY 2026 PFS proposed rule that the APP Plus quality measure set is duplicative of the health equity adjustment. However, in response to the comment that adding more measures will increase disparities and heighten the need for the health equity adjustment, as described at § 425.512(b)(4)(v), we clarify that the health equity adjustment is capped at 10 points. This cap was established when the health equity adjustment was finalized in performance year 2023 and was not designed to increase (or decrease) as the quality measure set expands (or contracts). As the number of measures in the APP Plus quality measure set increases, the health equity adjustment cap would become increasingly restrictive in its benefit. In contrast, the benefits of the eCQM/MIPS CQM reporting incentive and flat benchmarks for Medicare CQMs policy are not limited by an increase in the APP Plus quality measure set. While the Complex Organization Adjustment does have a cap as described at § 414.1380(b)(1)(vii)(C), the cap is relative to the total available measure achievement points, and by design, would increase or decrease based on the number of measures being scored. For these reasons, we believe that the eCQM/MIPS CQM reporting incentive, Complex Organization Adjustment, and flat benchmarks for Medicare CQMs are more appropriate policies for supporting ACOs as the APP Plus quality measure set expands.

As stated in an earlier response, as the number of eCQMs that ACOs are required to report in the APP Plus quality set grows, the value of the Complex Organization Adjustment will increase such that ACOs will have the opportunity to earn more measure achievement points. We also noted that we are finalizing our proposal to remove Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set, as described in section III.F.6.d. of this final rule. Therefore, for performance year 2028 or the performance year that is one year after the eCQM specification becomes available for

Quality ID: 493 Adult Immunization Status, whichever is later, ACOs that report eCQMs would receive the Complex Organization Adjustment on up to seven measures (that is, seven points) if each eCQM meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Additionally, we stated in the CY 2025 PFS final rule (89 FR 98123) that we believe the increased number of quality measures that will be phased into the APP Plus quality measure set over time will afford ACOs expanded opportunities to satisfy the eCQM/MIPS CQM reporting incentive criteria.

Comment: A commenter stated that the removal of the health equity adjustment would overburden physicians.

Response: While the commenter did not explain why they believe that the removal of the health equity adjustment would overburden physicians, we disagree that it would do so. As we stated in the CY 2026 PFS proposed rule (90 FR 32679), we believe that removing the health equity adjustment applied to an ACO's quality score would simplify our quality scoring methodology for ACOs, while maintaining sufficient support for ACOs to meet the quality performance standard through the application of the eCQM/MIPS CQM reporting incentive, the Complex Organization Adjustment, and use of flat benchmarks for Medicare CQMs. Our proposal would allow ACOs and their participating providers to focus on a simpler scoring methodology that includes more widely applicable incentives, determine how to improve the quality of care furnished to their beneficiaries, and operate with greater focus to improve care coordination activities, thus resulting in the improvement of their performance on quality measures and ability to serve their beneficiaries.

Comment: Several commenters stated that the health equity adjustment aligns with CMS' goals to encourage accountable care providers to take on downside risk for vulnerable beneficiary populations.

Response: We note that there are existing Shared Savings Program policies that encourage ACOs to take on downside risks. Specifically, we direct commenters to the option to receive advanced investment payment as described at § 425.630. We note that, as stated in section III.F.2.(2) of this final rule, advance investment payments are designed to provide upfront funding to assist new, low -revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives. We believe this type of upfront funding can aid eligible ACOs in their development such that they could be able to take on downside risk a little more quickly.

We also direct readers to eligible ACOs' option to receive prepaid shared savings as described at § 425.640. We also note that, as stated in the CY 2025 PFS final rule (89 FR 98132), we believe that the option to receive prepaid shared savings will reduce barriers to participation in the Shared Savings Program for eligible ACOs by supporting investments in increased staffing, healthcare infrastructure, and the provision of accountable care for beneficiaries. While there are limitations on the use of prepaid shared savings, the option to receive prepaid shared savings is available to eligible ACOs participating in Levels C–E of the BASIC track or the ENHANCED track during the agreement period in which they would receive prepaid shared savings, provided they meet other applicable requirements. Additionally, we direct commenters to section III.F.8. of this final rule for a discussion on our policies related to the population adjustment to the historical benchmark. We believe that these policies sufficiently support ACOs in the assumption of risk, and the efficacy of these policies would not be impeded by our proposal to remove the health equity adjustment as discussed in detail in our aforementioned analyses, which indicated that historically, the removal of the health equity adjustment would not have prevented any ACOs that benefitted from the health equity adjustment to meet the quality performance standard.

Comment: Some commenters stated that removing the health equity adjustment signals to providers that equity is no longer a top priority in the Medicare program. A commenter urged CMS to find a better way to address health disparities. Some commenters believed the health equity adjustment aligns with the Administration's goals to improve health and prevent chronic illnesses as it can encourage new ACOs and support existing ACOs that serve beneficiaries at higher risk for developing chronic conditions.

Response: In the CY 2026 PFS proposed rule (90 FR 32678), we stated that we believe that the application of the Complex Organization Adjustment and the extension of the eCQM/MIPS CQM reporting incentive, as finalized in prior rules, have made it unnecessary to continue the policy of applying the health equity adjustment to an ACO's quality score. The Complex Organization Adjustment and the extension of the eCQM/MIPS CQM reporting incentive underscore our commitment to all payer/all patient quality measure reporting and are more broadly applicable than the health equity adjustment. As discussed later in this section, we are finalizing our proposal with modification to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2026. In

alignment with the Administration's priority to streamline regulations, our policy to remove the health equity adjustment would de-duplicate scoring factors and simplify our quality scoring methodology, without reducing the support available under our policies for ACOs to meet the quality performance standard and be eligible to receive maximum shared savings and avoid maximum shared losses (if applicable).

Comment: A commenter stated that it is inconsistent to remove the health equity adjustment while retaining the HEBA when, in the commenter's belief, they share the goal of supporting ACOs that serve vulnerable populations and incentivizing their long-term participation. Another commenter stated that retaining the HEBA but eliminating the health equity adjustment undermines CMS' stated policy goal of supporting ACOs that serve vulnerable population and incentivizing long-term participation of these ACOs.

Response: Our proposal to remove the health equity adjustment applied to an ACO's quality score is based on our conclusion that the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment provide duplicative incentives to the incentives provided by the health equity adjustment. In contrast, there are no Shared Savings Program financial benchmark adjustments that serve a similar function to the HEBA. We refer readers to section III.F.8. of this final rule for a discussion on our policies related to the population adjustment.

Comment: Several commenters opposed our proposal to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025. Several commenters encouraged CMS to retain the population and income adjustment bonus points for performance year 2025 and subsequent performance years, with other commenters urging CMS to expand the adjustment to all collection types. Several commenters stated that removing the adjustment, particularly retroactively 9 months into the reporting period, would create harm by making it more difficult for ACOs serving high proportions of dual eligible and Medicare Part D LIS beneficiaries to remain in the Shared Savings Program. A commenter noted that retroactively eliminating the adjustment adds uncertainty and financial risk, while another commenter had concerns about the retroactive change and noted that ACOs have already made strategic and financial decisions in anticipation of the health equity adjustment being available and that retroactive removal would create confusion and disrupt ongoing investments.

A commenter disagreed that the retroactive removal of the adjustment was in the public interest and noted that there is no evidence of "double payment" or additional cost to the Medicare Trust Fund, as CMS stated the health equity adjustment was not applied in cases where the eCQM/MIPS CQM reporting incentive was met. The commenter noted that CMS must demonstrate that no harm exists to justify retroactive elimination of the health equity adjustment and noted that CMS has not provided evidence that the health equity adjustment increases costs or undermines program integrity.

Response: In the CY 2026 PFS proposed rule (90 FR 32678), we stated that we believe it would be contrary to the public interest to apply the proposed removal of the health equity adjustment applied to an ACO's quality score prospectively only. As such, we proposed to apply the removal retroactively, beginning in performance year 2025. Additionally, we stated that we believe that it is in the public interest to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 to simplify our quality scoring methodology for ACOs, while maintaining sufficient support for ACOs to meet the quality performance standard through the application of the eCQM/MIPS CQM reporting incentive, the Complex Organization Adjustment, and use of flat benchmarks for Medicare CQMs. We stated that making this change retroactively would provide greater clarity for ACOs by establishing continuity in resource language between performance year 2025 and subsequent performance years, allowing ACOs to plan ahead and have additional time to update internal operations and more easily prepare for consistent quality performance standards.

We acknowledge the commenters' concerns related to the retroactive effective date for removing the health equity adjustment applied to an ACO's quality score beginning in performance year 2025. Therefore, we are finalizing our proposal with modification to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2026, instead of performance year 2025 as we proposed. We believe that revising the removal of the health equity adjustment to begin in performance year 2026 would address the commenters' concerns about the retroactive effective date interfering with the existing ACOs' operations, causing uncertainty for participants, and lacking clear benefit for all ACOs.

Section 1871(e)(1)(A)(ii) of the Act prohibits the Secretary from retroactively applying a substantive change in Medicare regulations unless failure to do so would be contrary to the public

interest. While we recognized in the CY 2026 PFS proposed rule that removing the health equity adjustment applied to an ACO's quality score beginning in performance year 2025 could promote consistency and simplification in scoring methodology, upon further consideration, we conclude that these benefits are outweighed by the risks of altering incentives when the performance year is already underway. ACOs have already made decisions based on the availability of the health equity adjustment for performance year 2025, and retroactive removal could create unnecessary disruption.

We discussed earlier in this section of the final rule that, since the publication of the CY 2026 PFS proposed rule, the performance year 2024 ACO quality results have become available. We used this data to conduct simulations on how the removal of the health equity adjustment and the application of the eCQM/MIPS CQM reporting incentive, Complex Organization Adjustment, and flat benchmarking policies for Medicare CQMs would impact ACOs' quality scores. Based on our findings, we believe that the collective benefit of flat benchmarks for Medicare CQMs, in conjunction with the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment, would provide sufficient support to ACOs in performance year 2025 and subsequent performance years to substantiate the removal of the health equity adjustment. We acknowledge that ACOs will want to understand the specific impact of our new policies – notably, the extension of the eCQM/MIPS CQM reporting incentive, the Complex Organization Adjustment, and flat benchmarks for Medicare CQMs – on their ACO before the removal of the health equity adjustment. For this reason, and the reasons described in this section of this final rule, we are finalizing the removal of the health equity adjustment prospectively for performance year 2026, instead of retroactively for performance year 2025 as had been proposed.

We received a few comments on the health equity adjustment that we consider to be out of scope and will not be addressing these comments in this final rule.

After consideration of public comments, we are finalizing with modification our proposal to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2026. In alignment with this final policy, we are also finalizing with modification our proposed revisions to the terminology in the Shared Savings Program used to describe the health equity adjustment and other related terms for performance years 2023 through 2025, as discussed in section III.F.6.c.(3) of this final rule.

Specifically, we are finalizing with modification our proposal to revise and republish paragraph (b) of § 425.512, as follows:

- Commensurate with our modification to remove the health equity adjustment in performance year 2026 and not in performance year 2025 as had been proposed, we are not finalizing our proposal to remove § 425.512(b)(3). Instead, we are finalizing at § 425.512(b)(3) introductory text to remove the phrase "and subsequent performance years".

- We are not finalizing our proposal at § 425.512 to redesignate paragraph (b)(4) as paragraph (b)(3) and paragraph (b)(5) as paragraph (b)(4), respectively.

- We are not finalizing our proposal to revise references to § 425.512(b)(4) and (b)(5) (which we proposed to redesignate as paragraphs (b)(3) and (b)(4)).

- We are not finalizing our proposal at § 425.512(b)(4)(iv)(A)(*2*)(*ii*), and instead are finalizing to remove the phrase "For performance year 2024 and subsequent performance years" and add in its place the phrase "For performance years 2024 and 2025".

- We are making a change that was omitted from the CY 2026 PFS proposed rule to ensure consistency with existing regulation text in § 425.512(b)(4)(iv)(A)(*1*)(ii) and (b)(4)(iv)(A)(*2*)(i) by finalizing the addition of clarifying text at § 425.512(b)(4)(iv)(A)(*2*)(*ii*) to align language within these paragraphs, namely to consolidate the terms "LIS" and "Medicare Part D LIS", which are synonyms in this context. Specifically, we are removing the phrase "LIS or dually eligible" and adding in its place the phrase "the Medicare Part D LIS or are dually eligible".

- We are not finalizing our proposed revisions to § 425.512(b)(5) introductory text and paragraph references.

(3) Revising the Terminology in the Shared Savings Program Regulations Used to Describe the Health Equity Adjustment and Other Related Terms

We stated in the CY 2026 PFS proposed rule (90 FR 32679 and 32680) that to accurately reflect the data used to calculate the health equity adjustment in performance years 2023 and 2024, we proposed to revise the terminology used to describe this adjustment and other related terms in the Shared Savings Program regulations. Previously, the term health equity was used in a broad way that could lead to confusion regarding whether or not impermissible features, such as race and ethnicity, were included in

Shared Savings Program policies (which they are not). We did not propose changes in the methodology currently used to calculate the health equity adjustment bonus points or the health equity adjusted quality performance score for performance years 2023 and 2024.

In revising the terminology used to describe the health equity adjustment, we found that our use of the terms "quality score" and "quality performance score" could lead to confusion. As such, we also proposed to revise the terms "quality score" and "quality performance score" at § 425.512. We proposed to apply the term "quality score" consistently throughout § 425.512 to mean an ACO-level quality score and also apply the term "quality performance score" to consistently mean a measure-level score.

Additionally, we proposed to update the cross-references in §§ 425.605 and 425.610 to reference the entirety of § 425.512. With respect to § 425.512(b), we note that the amendments are specified in revised and republished paragraph (b). Specifically, we proposed the following conforming revisions to terminology used in the Shared Savings Program at §§ 425.512, 425.605, and 425.610:

- At § 425.512 in paragraphs (a)(3)(i), (b)(5)(iv) (which, as discussed later in this section, we proposed to redesignate as paragraph (b)(4)(iv)), (c)(2)(i), (c)(2)(ii), and (c)(3)(i) remove the phrase "quality performance score" and add in its place the phrase "quality score".
- At § 425.512 in paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(1), (a)(5)(i)(B)(1), (a)(5)(i)(C)(1), (a)(7), (b)(1), (b)(2), (c)(3)(ii), (c)(3)(iii), and (c)(3)(iv) remove the phrase "health equity adjusted quality performance score" and add in its place the phrase "quality score".
- At § 425.512 in paragraph (b) subject heading revised to read as follows: "Calculation of an adjustment to an ACO's quality score for performance years 2023 and 2024".
- At § 425.512 in paragraphs (b)(1) and (b)(2), remove the phrase "health equity adjustment bonus points" and add in its place the phrase "population and income adjustment bonus points".
- At § 425.512 in paragraph (b)(4) (which we proposed to redesignate as paragraph (b)(3)), revise the introductory text to read as follows: "Calculation of ACO's population and income adjustment bonus points. CMS calculates the ACO's bonus points as follows:".
- At § 425.512 in paragraph (b)(4)(iv) (which we proposed to redesignate as paragraph (b)(3)(iv)), remove the phrase "an underserved multiplier" and add in its place the phrase "a multiplier".

- At § 425.512 in paragraph (b)(4)(iv)(A)(*1*) (which we proposed to redesignate as paragraph (b)(3)(iv)(A)(*1*)), remove the phrase "that is considered underserved".

- At § 425.512 in paragraph (b)(4)(iv)(B) (which we proposed to redesignate as paragraph (b)(3)(iv)(B)), remove the phrase "health equity adjustment bonus points" and add in its place the phrase "bonus points".

- At § 425.512 in paragraph (b)(4)(v) (which we proposed to redesignate as paragraph (b)(3)(v)): remove the phrase "underserved multiplier" and add in its place the phrase "multiplier"; and remove the phrase "health equity adjustment bonus points" and add in its place the phrase "bonus points".

- At § 425.605 in paragraphs (d)(1)(i)(A)(*3*)(*ii*), (d)(1)(i)(A)(*4*)(*ii*), (d)(1)(ii)(A)(*3*)(*ii*), (d)(1)(ii)(A)(*4*)(*ii*), (d)(1)(iii)(A)(*3*)(*ii*), (d)(1)(iii)(A)(*4*)(*ii*), (d)(1)(iv)(A)(*3*)(*ii*), (d)(1)(iv)(A)(*4*)(*ii*), (d)(1)(v)(A)(*3*)(*ii*), and (d)(1)(v)(A)(*4*)(*ii*) remove the phrase "health equity adjusted quality performance score calculated according to § 425.512(b)" and add in its place the phrase "quality score calculated according to § 425.512".

- At § 425.610 in paragraphs (d)(3)(ii), (d)(4)(ii), (f)(3)(i)(A) and (f)(4)(i)(A) remove the phrase "health equity adjusted quality performance score calculated according to § 425.512(b)" and add in its place the phrase "quality score calculated according to § 425.512".

We sought public comments on these proposed changes. These proposed terminology changes are reflected in the summaries of the quality reporting requirements and quality performance standards that we included in Tables 52 and 53 of the CY 2026 PFS proposed rule (90 FR 32683 through 32685).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to rename the "health equity adjustment bonus points" to the "population and income adjustment bonus points." Several commenters stated that the name change would enhance clarity and more accurately represent the policy of providing the opportunity to upwardly adjust the quality score for ACOs with complex beneficiary populations to reflect the additional challenges of serving these populations without sacrificing policy goals.

Response: We thank commenters for their support.

Comment: A commenter recommended that CMS rename the adjustment to a "population

adjustment to quality", since the term "health equity" may cause the public to inappropriately assume that the adjustment is based on race or ethnicity, when in fact the adjustment is not.

Response: We thank the commenter for the recommendation, but we believe that the proposed change in terminology from "health equity adjustment" to "population and income adjustment" will accurately reflect the data used to calculate the adjustment.

Comment: A commenter stated that replacing the health equity adjustment with a "population adjustment" does not offer the same level of focus or transparency on fairness in care delivery and that the new language risks weakening CMS' longstanding commitment to addressing inequities.

Response: We note that the proposed change in terminology from "health equity adjustment" to "population and income adjustment" will not change how the adjustment is calculated and will more accurately reflect the data used to calculate the adjustment.

As discussed in section III.F.6.c (2) of this final rule, we are finalizing with modification our proposal to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2026 (instead of performance year 2025 as proposed). In alignment with this finalized policy, we are finalizing with modification our proposed revisions to the terminology in the Shared Savings Program used to describe the health equity adjustment and other related terms for performance years 2023 through 2025 (instead of performance years 2023 and 2024 as proposed). There will be no changes in the methodology currently used to calculate the health equity adjustment bonus points or the health equity adjusted quality performance score for performance years 2023 through 2025.

We are finalizing as proposed to our proposed revisions of the terms "quality score" and "quality performance score" at § 425.512 to apply the term "quality score" consistently throughout § 425.512 to mean an ACO-level quality score and apply the term "quality performance score" to mean a measure-level score. Additionally, we are finalizing our proposal to update the cross-references in §§ 425.605 and 425.610 to reference the entirety of § 425.512. With respect to § 425.512(b), we note that the amendments are specified in revised and republished paragraph (b). These finalized changes are reflected in Tables X2 and X3 of this final rule.

Specifically, we are finalizing with modification the proposed revisions to terminology used in the Shared Savings Program at §§ 425.512, 425.605, and 425.610 to reflect that the health equity adjustment will be removed beginning in performance year 2026:

- As described in section III.F.6.c.(2) of this final rule, we are not finalizing our proposal at § 425.512(b)(3) to remove paragraph (b)(3) and are not finalizing our proposal at paragraphs (b)(4) and (b)(5) to redesignate paragraph (b)(4) as paragraph (b)(3) and paragraph (b)(5) as paragraph (b)(4), respectively.

- At § 425.512(a)(3)(i), (b)(5)(iv), (c)(2)(i), (c)(2)(ii), and (c)(3)(i) removing the phrase "quality performance score" and adding in its place the phrase "quality score".

- At § 425.512(a)(4)(i)(A), (a)(5)(i)(A)(1), (a)(5)(i)(B)(1), (a)(5)(i)(C)(1), (a)(7), (b)(1), (b)(2), (b)(3), (c)(3)(ii), (c)(3)(iii), and (c)(3)(iv) removing the phrase "health equity adjusted quality performance score" and adding in its place the phrase "quality score".

- At § 425.512(b) modifying the subject heading to read as follows: "Calculation of an adjustment to an ACO's quality score for performance years 2023 through 2025".

- At § 425.512(b)(3), removing the phrase "health equity adjusted quality performance score" and adding in its place the phrase "quality score".

- At § 425.512(b)(3), removing the phrase "health equity adjustment bonus points" and adding in its place the phrase "population and income adjustment bonus points".

- As described in section III.F.6.c.(2) of this final rule, at § 425.512(b)(3), removing from the introductory text the phrase "and subsequent performance years".

- At § 425.512(b)(1), (b)(2), and (b)(3) removing the phrase "health equity adjustment bonus points" and adding in its place the phrase "population and income adjustment bonus points".

- At § 425.512(b)(4), revising the introductory text to read as follows: "Calculation of ACO's population and income adjustment bonus points. CMS calculates the ACO's bonus points as follows:".

- At § 425.512(b)(4)(iv), removing the phrase "an underserved multiplier" and adding in its place the phrase "a multiplier".

- At § 425.512(b)(4)(iv)(A)(*1*), removing the phrase "that is considered underserved".

- At § 425.512(b)(4)(iv)(B), removing the phrase "health equity adjustment bonus points" and adding in its place the phrase "bonus points".

- At § 425.512(b)(4)(v): removing the phrase "underserved multiplier" and adding in its place the phrase "multiplier"; and removing the phrase "health equity adjustment bonus points" and adding in its place the phrase "bonus points".

- At § 425.605(d)(1)(i)(A)(*3*)(*ii*), (d)(1)(i)(A)(*4*)(*ii*), (d)(1)(ii)(A)(*3*)(*ii*), (d)(1)(ii)(A)(*4*)(*ii*), (d)(1)(iii)(A)(*3*)(*ii*), (d)(1)(iii)(A)(*4*)(*ii*), (d)(1)(iv)(A)(*3*)(*ii*), (d)(1)(iv)(A)(*4*)(*ii*), (d)(1)(v)(A)(*3*)(*ii*), and (d)(1)(v)(A)(*4*)(*ii*) removing the phrase "health equity adjusted quality performance score calculated according to § 425.512(b)" and adding in its place the phrase "quality score calculated according to § 425.512".

- At § 425.610(d)(3)(ii), (d)(4)(ii), (f)(3)(i)(A) and (f)(4)(i)(A) removing the phrase "health equity adjusted quality performance score calculated according to § 425.512(b)" and adding in its place the phrase "quality score calculated according to § 425.512".

d. Updating the APP Plus Quality Measure Set

(1) Background

In the CY 2026 PFS proposed rule (90 FR 32680), we stated that in the CY 2025 PFS final rule, we created the APP Plus quality measure set to align with the Adult Universal Foundation measures (89 FR 98356) and finalized a phase-in schedule for incorporating measures into the APP Plus quality measure set.

We finalized in the CY 2025 PFS final rule (89 FR 98105) that, for performance year 2025 and subsequent performance years, Shared Savings Program ACOs will be required to report the APP Plus quality measure set. We also finalized that Shared Savings Program ACOs will be required to report on and will be scored on all applicable quality measures in the APP Plus quality measure set according to the phase-in schedule for incorporating measures into the APP Plus quality measure set. We also stated in the CY 2025 PFS final rule (89 FR 98116 and 98117) that the APP Plus quality measure set for Shared Savings Program ACOs will include 11 measures (eight eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with performance year 2028 or the performance year that is one year after the eCQM specifications become available for Quality

ID: 487 Screening for the Social Drivers of Health and Quality ID: 493 Adult Immunization Status, whichever is later, and ACOs will be scored on the required 11 measures.

The final APP Plus quality measure set for Shared Savings Program ACOs, for performance year 2025 and subsequent performance years, was specified in Tables 39 through 42 of the CY 2025 PFS final rule (89 FR 98128 through 98132).

(2) Revisions

Proposed changes to the following measures that are included in the APP Plus quality measure set were discussed in the CY 2026 PFS proposed rule (90 FR 32705 and 32706):

- Breast Cancer Screening (Quality ID: 112)
- Colorectal Cancer Screening (Quality ID: 113)
- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134) (eCQM collection type only)
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484)
- Screening for Social Drivers of Health (Quality ID: 487)

Further discussion and our rationale for the proposed modification or removal of these measures was provided in Table Groups D and DD, and C, respectively, in Appendix 1 of the CY 2026 PFS proposed rule.

We stated in the CY 2026 PFS proposed rule (90 FR 32680) that with the proposed removal of Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in the CY 2026 PFS proposed rule (90 FR 32705 and 32706) and Table Group C in Appendix 1), we proposed that the APP Plus quality measure set for Shared Savings Program ACOs would include ten measures (seven eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493 Adult Immunization Status, whichever is later. ACOs would be scored on the required ten measures. The proposed APP Plus quality measure set for Shared Savings Program ACOs, for performance year 2028 or the performance year that

is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later, is specified in Table 51 of the CY 2026 PFS proposed rule (90 FR 32681).

As discussed in section XXX of this final rule, we are finalizing with modification the proposed changes to the following measures that are included in the APP Plus quality measure set:

- Breast Cancer Screening (Quality ID: 112)
- Colorectal Cancer Screening (Quality ID: 113)

We refer readers to section XXX of this final rule for a discussion of how we are finalizing as proposed the changes to the following measures that are included in the APP Plus quality measure set:

- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134) (eCQM collection type only)
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484)
- Screening for Social Drivers of Health (Quality ID: 487)

Further discussion and our rationale for the modification or removal of these measures is provided in Table Groups D and DD, and C, respectively, in Appendix 1 of this final rule.

With the removal of Quality ID: 487 Screening for Social Drivers of Health from the APP Plus quality measure set as described in section XXX and Table Group C in Appendix 1 of this final rule, the APP Plus quality measure set for Shared Savings Program ACOs will include ten measures (seven eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493 Adult Immunization Status, whichever is later. ACOs will be scored on the required ten measures. The final APP Plus quality measure set for Shared Savings Program ACOs, for performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later, is specified in Table B-G5 of this final rule.

TABLE B-G5: MEASURES INCLUDED IN THE APP PLUS QUALITY MEASURE SET FOR SHARED SAVINGS PROGRAM ACOs BEGINNING WITH PERFORMANCE YEAR 2028 OR THE PERFORMANCE YEAR THAT IS ONE YEAR AFTER THE ECQM SPECIFICATION BECOMES AVAILABLE FOR QUALITY ID: 493, WHICHEVER IS LATER

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
493	Adult Immunization Status	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

e. Adding a Web-based Survey Mode to the CAHPS for MIPS Survey

(1) Background

In the CY 2026 PFS proposed rule (90 FR 32682), we stated that the CAHPS for MIPS Survey is an annual survey available to MIPS groups in Traditional MIPS and MIPS Value Pathways (MVPs), and APM Entities. As required at § 425.510(b)(2), for performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367 according to the method of submission established by CMS. The CAHPS for MIPS Survey is a quality measure in the APP Plus quality measure set (89 FR 98367 through 98371). Therefore, Shared Savings Program ACOs are required to administer the CAHPS for MIPS Survey (except if an ACO does not meet the required sample size specified at § 414.1380(b)(1)(vii)(B)) to meet the quality reporting requirement under the Shared Savings Program. We stated that as of the CY 2026 PFS proposed rule, data was collected using a mail-phone survey administration protocol administered in English and Spanish, with additional translations available. We noted that the CAHPS for MIPS Survey may only be administered by CMS-approved survey vendors.

In the CY 2025 PFS proposed rule (89 FR 61869, 62042, and 62043), we included a request for information (RFI) on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. We solicited public comment on this new protocol given the positive results found from our 2023 CAHPS for MIPS Web Mode Field Test. The field test added the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS Survey administration, and we found that the addition resulted in an increased response rate (89 FR 62043). Commenters widely supported an expansion of CAHPS for MIPS Survey modes to include a web-based survey protocol, emphasizing that this could help increase response rates.

(2) Revisions

In the CY 2026 PFS proposed rule (90 FR 32682), we stated that based on the results of the field test, and informed by the responses from commenters in response to our RFI, we proposed to require that beginning with 2027, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. Additionally, under this proposal and pursuant to the policy we finalized in the CY 2025 PFS final rule to require, beginning with the 2026 performance period/2028

MIPS payment year, CMS-approved survey vendors to submit the range of costs of their services (89 FR 98459 and 98460), the cost of adding the web survey mode would be included as part of the overall costs of CAHPS for MIPS Survey administration publicly reported by vendors. We referred readers to the CY 2026 PFS proposed rule (90 FR 32768 and 32769) for additional information on this proposal.

We refer readers to section XXX of this final rule, where we are finalizing as proposed our proposal to require that beginning with 2027, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol.

f. Summary of Final Policies

In Tables 52 and 53 of the CY 2026 PFS proposed rule, we summarized the quality reporting requirements and quality performance standard policies for performance year 2025 and subsequent performance years, including our proposals in the CY 2026 PFS proposed rule.

In Tables B-G6 and B-G7 of this final rule, we summarize the quality reporting requirements and quality performance standard policies for performance year 2025 and subsequent performance years, including the policies we are finalizing in this final rule. Table B-G7 also reflects the removal of Quality ID: 487 Social Drivers of Health from the APP Plus quality measure set for Shared Savings Program ACOs, as discussed in section III.F.6.d. of this final rule, for performance year 2028 or the performance year that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later. These tables are same as Tables 52 and 53 of the CY 2026 PFS proposed rule (90 FR 32683 through 32685).

TABLE B-G6: APP PLUS QUALITY MEASURE SET REPORTING REQUIREMENTS AND QUALITY PERFORMANCE STANDARD POLICIES FOR SHARED SAVINGS PROGRAM ACOS FOR PERFORMANCE YEARS 2025 AND 2026

	Performance Year 2025	**Performance Year 2026**
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report the **4** eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 1 claims-based measure.	ACOs are required to report **5** eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding

	Performance Year 2025	Performance Year 2026
	entities/providers eligible for facility-based scoring, or 2. Reporting the 4 eCQMs/MIPS CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 4 eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 3 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 5 measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 3 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 4 eCQMs /MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	entities/providers eligible for facility-based scoring, or 2. Reporting the 5 eCQMs/MIPS CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 5 eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 7 measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 5 eCQMs /MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

TABLE B-G7: APP PLUS QUALITY MEASURE SET REPORTING REQUIREMENTS AND QUALITY PERFORMANCE STANDARD POLICIES FOR SHARED SAVINGS PROGRAM ACOs FOR PERFORMANCE YEAR 2027 AND SUBSEQUENT PERFORMANCE YEARS

	Performance Year 2027	**Beginning with Performance Year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493, whichever is later**
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report **6** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.	ACOs are required to report **7** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **6** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 6 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **8** measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the **7** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 7 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **9** measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of

	Performance Year 2027	Beginning with Performance Year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493, whichever is later
	the **6** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	the 7 eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

g. Toward Digital Quality Measurement in CMS Quality Programs including for the Medicare Shared Savings Program– Request for Information

In the CY 2026 PFS proposed rule (90 FR 32684), we discussed that as stated in the CY 2025 PFS final rule (89 FR 98106), CMS aims to fully transition to digital quality measurement (dQM) in CMS quality reporting and value-based purchasing programs. Including eCQMs as a collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set aligns with our goal to transition to digital quality measurement, including the alignment and development of Fast Healthcare Interoperability Resources® (FHIR®) standards and tools for eCQM reporting.

In support of these goals, we directed interested parties to the CY 2026 PFS proposed rule (90 FR 32710-32715), which contains a Request for Information (RFI) to gather public input on the transition to dQM for CMS programs and on our anticipated approach on the use of FHIR® standards in eCQM reporting. In that section, we described the current state and requested input on key components of the ongoing dQM transition related to FHIR®-based eCQMs for the Shared Savings Program and the MIPS quality performance category. These components include: (1) FHIR®-based eCQM conversion progress; (2) Data standardization for quality measurement and reporting; (3) The timeline under consideration for FHIR®-based eCQM reporting; (4) Measure development and reporting tools; and (5) FHIR® Reporting and Data Aggregation for ACOs.

We refer readers to section XXX of this final rule.

7. Revisions to the Extreme and Uncontrollable Circumstances Policies to Determine Quality and Financial Performance

a. Overview

In the CY 2026 PFS proposed rule (90 FR 32685 and 32686), we stated that in the interim final rule with comment period (IFC) entitled "Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017", which appeared in the December 26, 2017 **Federal Register** (82 FR 60912 through 60919) (herein referred to as the "December 2017 IFC"), we established automatic extreme and uncontrollable circumstances (EUC) policies under the Shared Savings Program for performance year 2017 due to the urgency of providing relief to ACOs impacted by natural disasters (Hurricanes Harvey, Irma, and Maria, and California wildfires). We agreed with interested parties that the financial and quality performance of ACOs located in areas subject to EUCs could be significantly and adversely affected. For example, natural disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals (82 FR 60913). We stated that these disruptions could hinder quality performance in ACOs and thus could result in shared losses for which the ACO might be held responsible (82 FR 60914).

Since their establishment, we have revised our EUC policies and expanded them in response to PHEs, to determine the duration of the PHE and the percentage of ACOs' performance year assigned beneficiary populations that were EUC-affected (83 FR 68037), and to specify policies for addressing the effect of EUCs on ACOs' quality performance (85 FR 27576 and 27577; 85 FR 84746).

The current Shared Savings Program quality and finance EUC policies at §§ 425.512(c), 425.605(f), and 425.610(i) have been for ACOs affected by natural disasters or PHEs as determined by the Quality Payment Program; however, current policies do not unambiguously address ACOs affected by an EUC due to a cyberattack, including ransomware/malware.

Cyberattacks, including ransomware/malware, can be circumstances that are outside of the ACO's control and may have several possible effects on our ability to accurately and effectively measure ACOs' quality performance. For instance, a breach of confidential medical records of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting. Cyberattacks could inhibit the operation of EHR systems and thus render data submitted by ACOs inaccurate and unusable; failure to report quality data that comes from EHR systems could cause ACOs to fail the Shared

Savings Program's quality reporting requirements and, therefore, fail to meet the quality performance standard. Further, for ACOs impacted by ransomware/malware, the medical records needed for quality reporting may be inaccessible. Effects due to cyberattacks, including ransomware/malware, on ACO participants and their beneficiary populations could impact the ACO's ability to successfully meet the Shared Savings Program quality performance standard.

Currently the Shared Savings Program's EUC policies regarding calculation of the ACO's quality performance score and mitigating shared losses for ACOs participating under a two-sided model are aligned with the Quality Payment Program's automatic EUC policy, to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. We believe that there is a need to revise the quality and finance EUC policies to plainly account for an ACO affected at the legal entity level by an EUC due to a cyberattack, including ransomware/malware, where such a determination is made by the Quality Payment Program through the MIPS EUC Exception application process.

b. Revisions to the EUC Policy to Determine Quality Performance

(1) Background

In the CY 2026 PFS proposed rule (90 FR 32686), we stated that the current Shared Savings Program quality EUC policies are codified in the regulation at § 425.512(c). These policies were described in the December 2017 IFC (82 FR 60912 through 60919), March 31, 2020 COVID-19 IFC (85 FR 19267 through 19268), CY 2021 PFS final rule (85 FR 84744 through 84747), and CY 2023 PFS final rule (87 FR 69857 through 69858). In the CY 2021 PFS final rule (85 FR 84744 through 84747),we established at § 425.512(c) that, for performance year 2021 and subsequent performance years, including the applicable quality data reporting period for the performance year, we use an alternative approach to calculating the quality score, as described at § 425.512(c), for ACOs affected by EUCs, instead of using the approach as described at § 425.512(a). We determine the ACO was affected by an EUC based on either of the following:

● Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an EUC.

● The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an EUC.

As we established in the CY 2022 PFS final rule (86 FR 65271 and 65272), if CMS determines the ACO meets these requirements, then CMS calculates the ACO's quality score based on the following: For performance year 2024 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year (§ 425.512(c)(2)(ii)).

Further, as stated in § 425.512(c)(3)(iv), if the ACO reports quality data on the APP Plus quality measure set, then CMS calculates the ACO's quality score based on the following: For performance year 2025 and subsequent performance years, if the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 and receives a MIPS quality performance category score, then CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

At § 425.512(c)(4), CMS applies determinations made under the Quality Payment Program with respect to—

● Whether an EUC has occurred; and

● The affected areas.

At § 425.512(c)(5), CMS has sole discretion to determine the time period during which an EUC occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

(2) Revisions

In the CY 2026 PFS proposed rule (90 FR 32686 through 32688), we proposed that, for performance year 2025 and subsequent performance years, we would expand the application of the quality and finance EUC policies to an ACO, as defined at § 425.20, and as an APM Entity as defined at § 414.1305, that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. Specifically, we proposed to add § 425.512(c)(1)(iii) to

state: For performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

We proposed that if an ACO is affected at the legal entity level (as the term is commonly used throughout 42 CFR part 425) by an EUC due to a cyberattack, including ransomware/malware, and wants relief from Shared Savings Program quality reporting requirements, then the ACO must submit a MIPS EUC Exception application to the Quality Payment Program as an APM Entity for the affected performance year. If the Quality Payment Program approves an ACO's MIPS EUC Exception application, as an APM Entity, for a cyberattack, including ransomware/malware, for the affected performance year, then we would apply the Shared Savings Program quality and finance EUC policies at §§ 425.512(c), 425.605(f), and 425.610(i) to provide relief to the ACO from the Shared Savings Program quality reporting requirements and mitigate shared losses for the affected performance year. Under our proposal, the Shared Savings Program would not apply the quality and finance EUC policies to an ACO that submits a MIPS EUC Exception application as an individual, group, or virtual group.

For information on how to submit a MIPS EUC Exception application for performance year 2025, ACOs can refer to the Quality Payment Program Exception Application website (https://qpp.cms.gov/mips/exception-applications?py=2025) and 2025 MIPS EUC Exception Guide (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3239/2025-MIPS-Extreme-and-Uncontrollable-Circumstances-Exception-Application-Guide.pdf*).

Under our proposal, in alignment with § 425.512(c)(3)(iv), beginning in performance year 2025, if an ACO with an approved MIPS EUC Exception application for a cyberattack, including ransomware/malware, reports the APP Plus quality measure set, meets the data completeness requirement at § 414.1340, and receives a MIPS quality performance category score, then we would use the higher of the ACO's quality score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. Under our proposal, in alignment with § 425.512(c)(2)(ii), if CMS determines the ACO meets the requirements of § 425.512(c)(1), then the ACO's minimum quality performance score would be set to the equivalent of the 40th percentile MIPS

quality performance category score, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. This proposal would allow an ACO affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, to meet the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track and to have any shared losses pro-rated based on the length of the cyberattack, including ransomware/malware, as described in the CY 2026 PFS proposed rule (90 FR 32688 through 32690).

In the CY 2026 PFS proposed rule (90 FR 32687), we stated that section 1871(e)(1)(A)(ii) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. We are aware that cyberattacks, including ransomware/malware, have increased in recent years. It is in the public interest to revise the Shared Savings Program quality and finance EUC policies (the latter of which we discussed in the CY 2026 PFS proposed rule (90 FR 32688 through 32690)) to expand the application of these policies to an ACO at the legal entity level that is affected by an EUC due to a cyberattack, including ransomware/malware, beginning in performance year 2025. Because ACOs rely heavily on digital infrastructure and third-party vendors, they are increasingly vulnerable to ransomware, data breaches, and system outages. Cyberattacks, including ransomware/malware, can severely disrupt care coordination, compromise patient data, and disrupt the patient care environment. These disruptions can delay necessary treatments or procedures and reduce the quality of care provided to beneficiaries. We have heard from ACOs that have experienced cyberattacks about the adverse impact on clinical processes. For example, we have heard from ACOs that as a result of a cyberattack, impacted systems were unavailable and manual processes were implemented, including moving to paper records for certain clinical processes in order to continue to provide patient care. For these reasons, we understand that cyberattacks can disrupt the patient care environment, and we want ACOs to be able to continue to prioritize patient care during and in the aftermath of a cyberattack. As such, we believe that it is in the public interest to provide relief from the Shared Savings Program quality reporting requirements and by mitigating shared losses to any ACO that has an approved MIPS EUC Exception application due to cyberattack during performance year 2025 so that those ACOs can prioritize patient care during and in the aftermath of a cyberattack.

A cyberattack could interfere with the operation of electronic health record systems, affect the integrity of the data used to meet quality reporting requirements, and as a result render ACOs unable to report data that is true, accurate, and complete. Failure to meet the quality performance standard could result in an ACO owing maximum shared losses through no fault of the ACO. If the result of a cyberattack is that an ACO cannot satisfactorily meet the quality performance standard, then the ACO may not receive funds they could otherwise use to reinvest into the ACO and continue to improve the quality of care provided. Therefore, should any ACOs experience a cyberattack during 2025, we do not believe it is in the best interest of an ACO's patient population to disadvantage an ACO from earning shared savings (or for an ACO to incur shared losses) as a result of a disruption caused by a cyberattack.

Additionally, a cyberattack could contribute to unpredictable changes to utilization and spending that may have an impact on expenditures for the applicable performance year beyond the ACO's control. The impact of cyberattacks on physician practices were underscored in a 2024 survey conducted by the American Medical Association, with 90% of respondents at the time of the survey noting that they continued to lose revenue from unpaid claims, 63% noted that they were losing revenue due to the inability to charge patient co-pays or remaining obligations, and 91% had to commit additional staff time and resources to complete revenue cycle tasks.[416] Additionally, 42 percent of respondents were unable to purchase supplies, 29 percent of respondents were reliant upon private bank loans to fund their practice operations, 42 percent of respondents noted patients were unable to access coverage and cost information, and 25 percent shared that patients at the time of the survey continued to face difficulties getting their prescriptions filled.[417] These examples illustrate how a cyberattack could impact clinical processes that could contribute to unpredictable utilization and spending. This unpredictable utilization could further skew the results of the data used for quality reporting and assessing whether ACOs met the quality performance standard. Coupled with the previously mentioned impact to data integrity due to the possible need to use paper records to collect and submit quality data, cyberattacks could cause ACOs to submit quality data that is not a true, accurate, and complete reflection of their quality performance.

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[416] American Medical Association (2024). *Change Healthcare cyberattack impact: Key takeaways from informal AMA follow-up survey,* available at https://www.ama-assn.org/system/files/change-healthcare-follow-up-survey-results.pdf.
[417] Ibid.

If cyberattacks occur during performance year 2025 and subsequent performance years, we do not wish to hold ACOs who are experiencing extreme and uncontrollable circumstances accountable to a quality performance standard that could be based on inaccurate assessment of their beneficiaries' utilization of care and to apply the Shared Savings Program finance EUC policies §§ 425.605(f), and 425.610(i) to 100 percent of the ACO's assigned beneficiaries when an ACO has a MIPS EUC Exception application for a cyberattack, including ransomware/malware. Thus, we believe it is in the public interest to grant ACOs who have an approved MIPS EUC application relief from the Shared Savings Program quality performance standard so that the standard is accurately assessed and ACOs are not held accountable to an inaccurate assessment of the quality of care they provide based on potentially skewed health care utilization as the result of a cyberattack and to provide relief to the ACO by mitigating shared losses for the affected performance year. Our proposal would grant relief to ACOs that submit a MIPS EUC Exception application to the Quality Payment Program for a cyberattack, including ransomware/malware, and for which the Quality Payment Program approves the ACO's MIPS EUC Exception application.

We proposed the following revisions to the Shared Savings Program regulation at § 425.512(b):

- We proposed to revise paragraph (b)(5)(iv) (which we proposed to redesignate as paragraph (b)(4)(iv)), to remove the reference to "paragraphs (c)(3)(ii) through (c)(3)(iv)" and add in its place reference to "paragraphs (c)(3)(ii) and (c)(3)(iii)" consistent with our proposal to limit the applicability of §425.512(b) to performance years 2023 and 2024, as discussed in the CY 2026 PFS proposed rule (90 FR 32688 through 32690).

We proposed the following revisions to the Shared Savings Program quality EUC regulation at § 425.512(c):

- We proposed to revise paragraph (c)(1) introductory text to read as follows, "CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on any of the following:"
- We proposed to add a new paragraph (c)(1)(iii) to establish that for performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

We sought public comments on the proposed changes to the quality EUC policy.

We received public comments on the proposed changes to the quality EUC policy. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposed changes to the quality EUC policy. Many commenters noted that our proposal provides a critical and necessary safeguard for ACOs and ensures the program accounts for modern operational realities. Commenters stated how cyberattacks are becoming increasingly prevalent against health care organizations, and these attacks interfere with ACOs' ability to comply with program requirements, such as, quality reporting. Several commenters appreciated CMS' recognition of the rapidly evolving technological environment and the fact that cyberattacks could occur regardless of whether an ACO is exercising appropriate care in securing health IT systems. A commenter expressed how given the significant operational and data integrity disruptions such events can cause, extending EUC protections in these scenarios is consistent with maintaining fair quality and financial performance assessments. Another commenter stated that this policy will help attract and retain ACO participation in the Shared Savings Program by making it easier for ACOs to recruit and retain patient populations, and to endure the challenges presented by a cyberattack.

Several commenters supported our proposal's protection of continuity of care for beneficiaries. Several commenters stated that it is not just the ACO that is victimized by a cyberattack, but an entire ecosystem of organizations, providers, and beneficiaries that come into contact with that ACO through the course of delivering healthcare. These commenters noted how offering relief during these events is critical to maintaining care continuity and protecting beneficiaries. Several other commenters stated that cyberattacks are increasingly disruptive to care delivery and data integrity, and providing relief to ACOs in these circumstances can help ensure that ACOs can continue to prioritize patient care without being unfairly penalized.

Response: We thank commenters for their support. As we stated in the CY 2026 PFS proposed rule (90 FR 32687), we are aware that cyberattacks, including ransomware/malware, have increased in recent years. Because ACOs rely heavily on digital infrastructure and third-party vendors, they are increasingly vulnerable to ransomware, data breaches, and system outages. Cyberattacks, including ransomware/malware, can severely disrupt care coordination, compromise patient data, and disrupt the

patient care environment. These disruptions can delay necessary treatments or procedures and reduce the quality of care provided to beneficiaries. We have heard from ACOs that have experienced cyberattacks about the adverse impact on clinical processes. Effects due to cyberattacks, including ransomware/malware, on ACO participants and their beneficiary populations could impact the ACO's ability to successfully meet the Shared Savings Program's quality reporting requirements and thus the quality performance standard. We agree with commenters that the proposed changes to the quality EUC policy can help ACOs maintain care continuity and prioritize patient care.

Comment: Several commenters agreed with our proposal to apply these policies beginning in performance year 2025 and stated that ACOs' reliance on digital infrastructure and third-party vendors make them increasingly vulnerable to cyberattacks, and it would not be in the best interest of an ACO's patient population to disadvantage an ACO from earning shared savings.

Response: We thank commenters for their support. In the CY 2026 PFS proposed rule (90 FR 32687), we explained our rationale for why it is in the public interest to revise the Shared Savings Program quality and finance EUC policies to expand the application of these policies to an ACO at the legal entity level that is affected by an EUC due to a cyberattack, including ransomware/malware, beginning in performance year 2025.

Comment: Several commenters supported our proposal to require that an ACO affected at the legal entity level by an EUC due to cyberattack to submit a MIPS EUC Exception application to the Quality Payment Program as an APM Entity. These commenters also supported our proposal on how quality performance would be determined under the quality EUC policy for an ACO with an approved MIPS EUC Exception application. Commenters noted that, if approved, CMS would provide relief from quality reporting requirements for the relevant performance year. The commenters stated that this approach would allow ACOs to attempt to report quality measures for the affected performance year without putting their performance in the program in jeopardy.

Response: We thank commenters for their support.

Comment: A commenter supported the proposed changes to the quality EUC policy, but stated that they do not believe that cyberattacks are uncontrollable, and that organizations can and must take the necessary steps to protect the vital and sensitive health information of the patients under their care.

Response: We agree that ACOs must take steps to protect their patients' health information, including implementing practices and systems to protect against cyberattacks, including ransomware/malware. We note that, as described at § 425.700(b), CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data use agreement described in 42 CFR 425 subpart H. As we stated in the CY 2026 PFS proposed rule (90 FR 32686), we understand that there can be circumstances of cyberattacks, including ransomware/malware, that are outside of the ACO's control, which informed our proposed EUC policies.

Comment: A commenter recommended that CMS clarify the reporting process when a partial EUC is granted (that is, when an EUC is approved for an individual clinician or group). The commenter provided two alternative options for consideration. The first option would be to adjust the policy such that when any member TIN is approved for an EUC, the entire ACO is granted the EUC and is exempt from submitting data for that performance year. The second option would be to adjust the policy to allow the ACO to submit its APP Plus quality measure set data for all unaffected member TINs, such that the data from the impacted TIN would be excluded from the ACO's data completeness and performance calculations without penalty. Another commenter recommended CMS establish an option for ACO participants to file a MIPS EUC Exception application for the quality performance category at the NPI or TIN level, citing how if approved, this would remove the requirement for the ACO to report 100% of eligible patients from those EUC-approved providers, while still allowing the ACO to submit and report data for all other participants.

Response: We stated in the CY 2026 PFS proposed rule (90 FR 32686) that, if an ACO is affected at the legal entity level by an EUC due to a cyberattack, including ransomware/malware, and wants relief from Shared Savings Program quality reporting requirements, then the ACO must submit a MIPS EUC Exception application to the Quality Payment Program as an APM Entity for the affected performance year. If the Quality Payment Program approves an ACO's MIPS EUC Exception application, as an APM Entity, for a cyberattack, including ransomware/malware, for the affected

performance year, then we would apply the Shared Savings Program quality and finance EUC policies at §§ 425.512(c), 425.605(f), and 425.610(i) to provide relief to the ACO from the Shared Savings Program quality reporting requirements and mitigate shared losses for the affected performance year. Under our proposal, the Shared Savings Program would not apply the quality and finance EUC policies to an ACO that submits a MIPS EUC Exception application as an individual, group, or virtual group. Applying an individual or group-level exemption (at the NPI or TIN level) to a policy that governs reporting at the ACO level would be inconsistent with the structure of quality reporting under the Shared Savings Program, where the ACO is required to report quality data on behalf of all of its participants. The recommendations suggested by commenters could result in applying the quality and finance EUC policies to an ACO entity that was not directly impacted by a cyberattack, including ransomware or malware.

Comment: A commenter recommended that CMS add a grace period to provide relief for quality reporting in the year the cyberattack occurs.

Response: We interpret the commenter's use of "grace period" as a request for additional time after the cyberattack occurs to submit a MIPS EUC Exception application. We do not agree with the commenter's recommendation to add a grace period to provide relief for quality reporting. The MIPS EUC Exception application for a performance year is typically available until the last day of the performance year. For example, the MIPS EUC Exception application for performance year 2025 will be available until 8 p.m. ET on December 31, 2025. This timing is intended to prevent delays in the calculation of an ACO's quality score and financial reconciliation calculations.

Comment: A commenter recommended that CMS provide clear guidance on documentation requirements and timelines for MIPS EUC Exception applications to avoid delays in relief.

Response: Updated information on documentation and timelines for MIPS EUC Exception applications for ACOs impacted by a cyberattack, including ransomware/malware, that want to submit a MIPS EUC Exception application for performance year 2025, will be available on the Quality Payment Program Exception Application website https://qpp.cms.gov/mips/exception-applications?py=2025 after the release of this final rule.

We also sought comment on whether there are other scenarios we should consider recognizing under the Shared Savings Program quality and finance EUC policies, while safeguarding against overly

broad EUC policies that would allow ACOs to circumvent quality reporting requirements or avoid shared losses.

We received public comments on other scenarios that the commenters suggested we should consider recognizing under the Shared Savings Program quality and finance EUC policies.

Comment: A commenter recommended CMS expand the EUC policy to allow an ACO to request an exemption for member TINs whose clinical specialty is 100% misaligned with the required APP measures and who are unable to report on the required measures. Another commenter stated that CMS should also consider other instances where an ACO may miss a quality reporting deadline citing how good faith efforts to meet reporting deadlines by ACO's with positive compliance histories should be considered. A commenter urged CMS to continue monitoring health care developments and revise EUC policies as applicable to ensure patients receive necessary and timely care with minimal disruptions.

Response: We thank commenters for their suggestions.

We received a few comments on the proposed changes to the quality EUC policy that we consider to be out of scope and will not be addressing these comments in this final rule.

After consideration of public comments, we are finalizing the proposed changes to the quality EUC policy as proposed. For performance year 2025 and subsequent performance years, we will expand the application of the quality and finance EUC policies to an ACO, as defined at § 425.20, and as an APM Entity as defined at § 414.1305, that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. Specifically, we will add § 425.512(c)(1)(iii) to state: For performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

If an ACO is affected at the legal entity level (as the term is commonly used throughout 42 CFR part 425) by an EUC due to a cyberattack, including ransomware/malware, and wants relief from Shared Savings Program quality reporting requirements, then the ACO must submit a MIPS EUC Exception application to the Quality Payment Program as an APM Entity for the affected performance year. If the Quality Payment Program approves an ACO's MIPS EUC Exception application, as an APM Entity, for a cyberattack, including ransomware/malware, for the affected performance year, then we will apply the

Shared Savings Program quality and finance EUC policies at §§ 425.512(c), 425.605(f), and 425.610(i) to provide relief to the ACO from the Shared Savings Program quality reporting requirements and mitigate shared losses for the affected performance year. Under our final policy, the Shared Savings Program will not apply the quality and finance EUC policies to an ACO that submits a MIPS EUC Exception application as an individual, group, or virtual group.

We are finalizing that, in alignment with § 425.512(c)(3)(iv), beginning in performance year 2025, if an ACO with an approved MIPS EUC Exception application for a cyberattack, including ransomware/malware, reports the APP Plus quality measure set, meets the data completeness requirement at § 414.1340, and receives a MIPS quality performance category score, then we will use the higher of the ACO's quality score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. We are finalizing that if CMS determines the ACO meets the requirements of § 425.512(c)(1), then, in alignment with § 425.512(c)(2)(ii) (as amended by this final rule), the ACO's minimum quality score will be set to the equivalent of the 40th percentile MIPS quality performance category score, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. This policy will allow an ACO affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, to meet the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track and to have any shared losses pro-rated based on the length of the cyberattack, including ransomware/malware, as described elsewhere is section III.F.7 of this final rule.

We are also finalizing with modification the revisions to cross-references within the Shared Savings Program regulation at § 425.512(b). Currently, the provision in § 425.512(b)(5)(iv) specifies CMS' application of the health equity adjustment (being renamed the "population and income adjustment" as described elsewhere in this final rule) in determining the quality performance score for certain ACOs affected by extreme and uncontrollable circumstances, by performance year, described in § 425.512(c)(3)(ii)-(iv). We are not finalizing our proposal to revise paragraph (b)(5)(iv) (which we proposed to redesignate as paragraph (b)(4)(iv)) to remove the reference to "paragraphs (c)(3)(ii) through (c)(3)(iv)" and add in its place the reference to "paragraphs (c)(3)(ii) and (c)(3)(iii)". Consistent with our

modifications to limit the applicability of §425.512(b) to performance years 2023 through 2025, as discussed in section III.F.6.c.(2) of this final rule, we are not redesignating paragraph (b)(5)(iv) as paragraph (b)(4)(iv), because we are not removing paragraph (b)(3) as proposed, and therefore we do not need to renumber the paragraphs that follow (b)(3). We are finalizing, as a conforming change, an amendment to § 425.512(b)(5)(iv) to remove the reference "paragraphs (c)(3)(ii) through (iv) of this section" and add in its place the reference "paragraphs (c)(3)(ii) through (iv) of this section (as applicable)". This change in the phrasing of the reference provides clarity since § 425.512(c)(3)(iv) applies for performance year 2025 and *subsequent performance years* (emphasis added in italics), and performance year 2025 is the final year to which the population and income adjustment will apply.

We are finalizing the following revisions to the Shared Savings Program quality EUC regulation at § 425.512(c) as proposed:

- We are revising paragraph (c)(1) introductory text to read as follows, "CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on any of the following:"
- We are adding a new paragraph (iii) to (c)(1) to establish that for performance year 2025 and subsequent performance years, the ACO, as defined at §425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

c. Revisions to the EUC Policy to Determine Financial Performance

(1) Background

In the CY 2026 PFS proposed rule (90 FR 32688), we stated that the December 2017 IFC established policies for assessing the financial and quality performance of Shared Savings Program ACOs that were affected by EUCs during performance year 2017. These policies, and their subsequent revisions, are equally applicable for the finance EUC policies.

We further refined the finance EUC policies in the May 8, 2020 COVID-19 IFC (85 FR 27550), where we clarified the applicability of the program's EUC policy to mitigate shared losses for the period of the PHE for COVID-19 starting in January 2020. We explained that catastrophic events outside an ACO's control could increase the difficulty of coordinating care for patient populations and, due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a

significant impact on expenditures for the applicable performance year (85 FR 27577). These factors could jeopardize the ACO's ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program (85 FR 27577).

Under our current policies at §§ 425.605(f)(2) and 425.610(i)(2), ACOs (as defined at § 425.20) that CMS determines to have been affected by an EUC will have their shared losses (if applicable) reduced by an amount that is proportional to the percentage of the year (determined by total months) affected by the EUC(s) and the percentage of the ACO's performance year-assigned beneficiaries residing in EUC-affected areas.

At §§ 425.605(f)(3) and 425.610(i)(3), we apply determinations made by the Quality Payment Program with respect to the following:

- Whether an extreme uncontrollable circumstance has occurred; and
- The affected areas

At §§ 425.605(f)(4) and 425.610(i)(4), CMS has sole discretion to determine the time period during which an EUC occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

(2) Revisions

In the CY 2026 PFS proposed rule (90 FR 32688), we stated that if the Quality Payment Program approves an ACO's MIPS EUC Exception application, as an APM Entity, for a cyberattack, including ransomware/malware, for the affected performance year, we proposed to apply the Shared Savings Program finance EUC policies at §§ 425.605(f) and 425.610(i) to provide relief to the ACO by mitigating shared losses for the affected performance year.

In the CY 2026 PFS proposed rule (90 FR 32688), we stated that currently ACOs that we determine to have been affected by an EUC will have their shared losses (if applicable) reduced by an amount that is proportional to the percentage of the year (determined by total months) affected by the EUC(s) and the percentage of the ACO's performance year-assigned beneficiaries residing in EUC-affected areas. Unlike the determination of an EUC for a natural disaster or PHE that distinguishes the geographic locations impacted by the EUC, the MIPS EUC Exception application captures the APM

Entity's (such as an ACO's) request for the EUC but does not differentiate geographic area(s) impacted by the EUC. Therefore, we would be unable to determine the percentage of the ACO's performance year-assigned beneficiaries residing in an EUC-affected area based on the ACO's submission of an EUC application to the Quality Payment Program in the case of a cyberattack, including ransomware/malware. So, we proposed to apply the Shared Savings Program finance EUC policies §§ 425.605(f), and 425.610(i) to 100 percent of the ACO's assigned beneficiaries when an ACO has a MIPS EUC Exception application for a cyberattack, including ransomware/malware, approved by the Quality Payment Program for the affected performance year.

The MIPS EUC Exception application contains fields that allow an ACO to enter both a start date and an end date for the EUC. The application allows an ACO to provide either a start date and an end date or a start date only (if the EUC still persists at the time the application is submitted to CMS). We proposed that if an ACO provides a start date and an end date for the EUC in its application to the Quality Payment Program, then we would use those dates to determine the duration of the EUC. The start date must be provided in the application. The end date may also be provided in the application but is not required. An ACO may subsequently update the end date by contacting the Quality Payment Program Service Center.

We further proposed that, if an ACO does not provide an end date in the ACO's MIPS EUC Exception application or by contacting the Quality Payment Program Service Center to provide an end date prior to the end of the application submission period, then we would apply a 90-day default duration for purposes of mitigating shared losses. This 90-day default duration is consistent with the timeframe used for determining a PHE declaration by the Secretary (the declaration lasts for the duration of the emergency or 90 days but may be extended by the Secretary).[418]

We proposed that if the ACO's MIPS EUC Exception application has a start date that occurs less than 90 days before the end of the performance year, and the ACO's MIPS EUC Exception application does not include an end date for the EUC and the ACO does not provide an end date to CMS in the form and manner CMS specifies, then we proposed that December 31 of the performance year would be the

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[418] See *Administration for Strategic Preparedness & Response* website, *Declarations of a Public Health Emergency* webpage, at https://aspr.hhs.gov/legal/PHE/pages/default.aspx (describing duration of a public health emergency, among other information).

end date for which the ACO was impacted by the EUC, since that is when both the MIPS EUC Exception and the performance year used to calculate shared savings and shared losses end.

We proposed that if an ACO is affected by an EUC that persists from one performance year to a subsequent performance year, then the ACO would be required to submit a MIPS EUC Exception application for each affected performance year.

Moreover, as we discussed in the December 2017 IFC (82 FR 60916 through 60917), to exercise our authority under section 1899(i)(3) of the Act to use other payment models, we must demonstrate that the payment model— (1) ". . . does not result in spending more for such ACO for such beneficiaries than would otherwise be expended . . . if the model were not implemented. . . ." and (2) "will improve the quality and efficiency of items and services furnished under" Medicare. As described in CY 2026 PFS proposed rule (90 FR 32687) rule, we assessed the impacts of our proposal for mitigating shared losses for ACOs affected by extreme and uncontrollable circumstances due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. We considered the following: the impact of the potential loss of participation in the program by ACOs affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, should we not implement the policy described in the CY 2026 PFS proposed rule (90 FR 32687), and the anticipated minimal impact of adjusting losses for ACOs affected by a cyberattack, including ransomware/malware, as determined by the Quality Payment Program. On the basis of this assessment, we believe incorporating this extreme and uncontrollable circumstances policy into the payment methodologies would meet the requirements of section 1899(i) of the Act by not increasing expenditures above the costs that would be incurred under the statutory payment methodology under section 1899(d) of the Act and by encouraging affected ACOs to remain in the program, which we believe will increase the quality and efficiency of the items and services furnished to the beneficiaries they serve. For these reasons, we conclude that our proposal is permissible under our authority as described in section 1899(i)(3) of the Act.

In the CY 2026 PFS proposed rule (90 FR 32689), we proposed the following revisions to the Shared Savings Program finance EUC regulations at §§ 425.605 and 425.610:

- At § 425.605, to add paragraph (f)(2)(ii) to read as follows, "For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an

extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area."

- At § 425.605, to revise paragraph (f)(3) to read as follows, "CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):"
- At § 425.605, to remove the punctuation "; and" at the end of paragraph (f)(3)(i) and adding in its place a period.
- At § 425.605, to add a new paragraph (f)(3)(iii) to indicate the following: "The time period during which the ACO was affected by a cyberattack, including ransomware/malware."
- At § 425.605, to redesignate the paragraph (f)(4) as paragraph (f)(5).
- At § 425.605, to add a new paragraph (f)(4) to indicate the following: CMS will determine the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

++ At § 425.605(f)(4)(i), CMS will use the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

++ At § 425.605(f)(4)(ii), except as specified in paragraph (f)(4)(iii), if no end date is indicated on the ACO's application or otherwise provided to us in a form and manner specified by us, described in paragraph (f)(4)(i), we will apply a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

++ At § 425.605(f)(4)(iii), if the start date indicated on the ACO's application described in paragraph (f)(4)(i), is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, we will apply an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

- At § 425.610, to add paragraph (i)(2)(ii) to read as follows, "For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area."

- At § 425.610, to revise paragraph (i)(3) to read as follows, "CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):"

- At § 425.610, to remove the punctuation "; and" at the end of paragraph (i)(3)(i) and adding in its place a period.

- At § 425.610, to add a new paragraph (i)(3)(iii) to read as follows: "The time period during which the ACO was affected by a cyberattack, including ransomware/malware."

- At § 425.610, to add a new paragraph (i)(4) to indicate the following: CMS will determine the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

++ At § 425.610(i)(4)(i), we will use the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

++ At § 425.610(i)(4)(ii), and except as specified in paragraph (i)(4)(iii), if no end date is indicated on the ACO's application or otherwise provided to us in a form and manner specified by us, described in paragraph (i)(4)(i), we will apply a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

++ At § 425.610(i)(4)(iii), if the start date indicated on the ACO's application described in paragraph (i)(4)(i) is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS will apply an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

- To redesignate paragraph (i)(4) as paragraph (i)(5).

We sought public comments on these proposed changes to the finance EUC policies.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to apply Shared Savings Program EUC finance policies to 100 percent of an ACO's assigned beneficiaries when the ACO has an approved MIPS EUC Exception application for a cyberattack. Multiple commenters recommended that CMS finalize this policy as proposed. A commenter cited that it is beneficial that ACOs are not inappropriately penalized for cyberattacks that may impact ACO performance as cyberattacks may occur regardless of whether an ACO is exercising appropriate care in securing heath IT systems. Another commenter supported the proposal and cited their appreciation of CMS' recognition of the rapidly evolving technological environment. Additionally, a commenter urged CMS to finalize these policies as proposed and applauds CMS' efforts to safeguard ACOs from risking earned shared savings. Another commenter urged CMS to finalize all proposed EUC policy changes related to cyberattacks, citing that these policies will offer much-needed protection and flexibility to ACOs as impacted entities navigate the increasing risks of cybersecurity threats while continuing to deliver accountable care.

Response: We thank commenters for their support.

Comment: Some commenters supported CMS' proposed approach to determine the proportion of the performance year affected by the EUC due to cyberattack using the start and end dates provided on the ACO's EUC Exception application or defaulting to a 90-day duration when no end date is included, unless the start date is less than 90 days from the end of the performance year. A few of these commenters also encouraged CMS to communicate to ACOs that are affected by an EUC over multiple performance years that they must submit multiple MIPS EUC Exception applications to have relief from quality reporting requirements and mitigation of any shared losses for the duration of the EUC due to cyberattack. A commenter supported CMS' proposal to expand EUC policies and recommended that CMS provide clear guidance on documentation requirements and timelines for MIPS EUC Exception applications to avoid delays in relief.

Response: We thank commenters for their support. Updated information and communications will be available on the Quality Payment Program Exception Application website (*https://qpp.cms.gov/mips/exception-applications?py=2025)* after the release of this final rule. We also note that under the proposal, in alignment with the QPP, if an ACO is affected by an EUC that persists from one performance year to a subsequent performance year, then the ACO would be required to submit a MIPS EUC Exception application for each affected performance year.

Comment: A commenter supported CMS' proposal to expand EUC policies and encouraged CMS to revise the provision requiring a MIPS EUC Exception application to be resubmitted if it extends across two years to instead allow a single application to cover the full 90-day period, even if it spans two calendar years. The commenter cited that by revising the provision to allow a single application to cover the full 90-day period, even if it spans two calendar years, CMS would bring this proposal in line with other EUC provisions concerning the 90-day relief period.

Response: We stated in the CY 2026 PFS proposed rule (90 FR 32352) that if an ACO is affected at the legal entity level by an EUC due to a cyberattack, including ransomware/malware, and seeks relief from Shared Savings Program quality reporting requirements, then the ACO must submit a MIPS EUC Exception application to the Quality Payment Program as an APM Entity for the affected performance year. The MIPS EUC Exception utilizes performance years as the term of relevance; this policy aligns with the QPP requirements for the Exception Application[419]. Under our proposal, in alignment with the QPP, if an ACO is affected by an EUC that persists from one performance year to a subsequent performance year, then the ACO would be required to submit a MIPS EUC Exception application for each affected performance year.

For information on how to submit a MIPS EUC Exception application for performance year 2025, ACOs can refer to the Quality Payment Program Exception Application website (https://qpp.cms.gov/mips/exception-applications?py=2025) and 2025 MIPS EUC Exception Guide (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3239/2025-MIPS-Extreme-and-Uncontrollable-Circumstances-Exception-Application-Guide.pdf).*

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[419] See the *Quality Payment Program* website, *Quality Payment Program Exception Application*s webpage, at https://qpp.cms.gov/mips/exception-applications#mipseucexception-2025 (describing QPP exception guidelines by performance year).

After consideration of public comments, we are finalizing our proposed amendments to §§ 425.605 and 425.610 to expand the application of the Shared Savings Program finance EUC policies to an ACO as defined at § 425.20 that is affected by an EUC due to a cyberattack, including ransomware/malware, and has an approved MIPS EUC Exception application as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years . We note that in the CY 2026 PFS proposed rule there were minor, inadvertent discrepancies between the proposed amendments to the provisions of § 425.605(f) and § 425.610(i) (90 FR 32857 through 32859), and the preamble descriptions of these proposed changes to the regulation (90 FR 32689 and 32690). To follow is a list of amendments to the Shared Savings Program regulations specifying the finance EUC policies at § 425.605(f) and § 425.610(i) which we are finalizing with this final rule, with corrections to the descriptions of these amendments for clarity.

- At § 425.605, we are adding paragraph (f)(2)(ii) to read as follows: "For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area."
- At § 425.605, we are revising paragraph (f)(3) introductory text to read as follows:[420] "CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):"
- At § 425.605, we are removing the punctuation "; and" at the end of paragraph (f)(3)(i) and adding in its place a period.
- At § 425.605, we are adding a new paragraph (f)(3)(iii) to indicate the following: "The time period during which the ACO was affected by a cyberattack, including ransomware/malware."
- At § 425.605, we are redesignating paragraph (f)(4) as paragraph (f)(5).

[420] In describing this proposed change in preamble of the CY 2026 PFS proposed rule (90 FR 32689), we did not specify the revisions were to the introductory text of paragraph § 425.605(f)(3), although we provided this specificity in the amendatory instructions for the proposed provision (90 FR 32857).

● At § 425.605, we are adding a new paragraph (f)(4) to indicate the following: CMS determines the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

++ We are specifying at § 425.605(f)(4)(i), CMS uses the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

++ We are specifying at § 425.605(f)(4)(ii), except as specified in paragraph (f)(4)(iii) of this section, if no end date is indicated on the ACO's application or otherwise provided to CMS in a form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, CMS applies a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

++ We are specifying at § 425.605(f)(4)(iii), if the start date indicated on the ACO's application described in paragraph (f)(4)(i) of this section is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, CMS applies an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

● At § 425.610, we are adding paragraph (i)(2)(ii) to read as follows: "For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area."

- At § 425.610, we are revising paragraph (i)(3) introductory text to read as follows:[421] "CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):"

- At § 425.610, we are removing the punctuation "; and" at the end of paragraph (i)(3)(i) and adding in its place a period.

- At § 425.610, we are adding a new paragraph (i)(3)(iii) to read as follows: "The time period during which the ACO was affected by a cyberattack, including ransomware/malware."

- At § 425.610, we are redesignating paragraph (i)(4) as paragraph (i)(5).

- At § 425.610, we are adding a new paragraph (i)(4) to indicate the following: CMS determines the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

++ We are specifying at § 425.610(i)(4)(i), CMS uses the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

++ We are specifying at § 425.610(i)(4)(ii), except as specified in paragraph (i)(4)(iii) of this section, if no end date is indicated on the ACO's application or otherwise provided to CMS in a form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS applies a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

++ We are specifying at § 425.610(i)(4)(iii), if the start date indicated on the ACO's application described in paragraph (i)(4)(i) of this section is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS applies an end date of

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[421] In describing this proposed change in preamble of the CY 2026 PFS proposed rule (90 FR 32689), we did not specify the revisions were to the introductory text of paragraph § 425.610(i)(3), although we provided this specificity in the amendatory instructions for the proposed provision (90 FR 32858).

December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

d. Scenarios for the Start and End Dates Provided by ACOs when the MIPS EUC Exception Application is Submitted to CMS

In the CY 2026 PFS proposed rule (90 FR 32690), we provided the following scenarios on how we would apply the proposed quality and finance EUC policies to ACOs affected by an EUC due to a cyberattack, including ransomware/malware. We did not receive any comments on these scenarios. We are finalizing our quality and finance EUC proposals as proposed, so the following scenarios reflect the application of the finalized policies.

Scenario 1: ACO provides a start date and end date for the EUC in the application, or the ACO contacts the Quality Payment Program Service Center to provide an end date for the EUC prior to the end of the application submission period

- Application of the quality EUC policy: The quality EUC policy would apply to the ACO for the entire performance year, where we would use the higher of the ACO's quality score (if the ACO reports quality data on the APP Plus quality measure set) or the equivalent of the 40th percentile MIPS quality performance category score, as established at § 425.512(c)(3)(iv).
- Application of the finance EUC policies: The finance EUC policies as established at § 425.605 and § 425.610 would apply for the timeframe captured by the start and end date for the EUC and would apply to 100 percent of the ACO's assigned beneficiaries for the duration of the EUC.

Scenario 2: ACO provides a start date of March 1 for the EUC, but no end date in the application and the ACO does not contact the Quality Payment Program Service Center to provide an end date prior to the end of the application submission period

- Application of the quality EUC policy: The quality EUC policy would apply to the ACO for the entire performance year, where we would use the higher of the ACO's quality score (if the ACO reports quality data on the APP Plus quality measure set) or the equivalent of the 40th percentile MIPS quality performance category score, as established at § 425.512(c)(3)(iv).
- Application of the finance EUC policies: The finance EUC policies as established at §§ 425.605 and 425.610 would apply a start date of March 1 and an end date that would be 90 days from

the start date and will apply to 100 percent of the ACO's assigned beneficiaries for the duration of the EUC.

Scenario 3: ACO provides a start date of November 1 for the EUC, but no end date in the application and the ACO does not contact the Quality Payment Program Service Center to provide an end date prior to the end of the application submission period

- Application of the quality EUC policy: The quality EUC policy would apply to the ACO for the entire performance year, where CMS would use the higher of the ACO's quality score (if the ACO reports quality data on the APP Plus quality measure set) or the equivalent of the 40th percentile MIPS quality performance category score, as established at § 425.512(c)(3)(iv).
- Application of the finance EUC policies: The finance EUC policies as established at §§ 425.605 and 425.610 would apply a start date of November 1 and an end date of December 31, which is the last day of the performance year, and will apply to 100 percent of the ACO's assigned beneficiaries for the duration of the EUC.

8. Population Adjustment – Financial Benchmarking Methodology

a. Overview

In the CY 2025 PFS final rule (89 FR 98574 through 98576), we finalized the Health Equity Benchmark Adjustment (HEBA), aimed at increasing participation in the Shared Savings Program by ACOs that serve an above-average proportion of Medicare Part D enrollees receiving Low Income Subsidy (LIS) or dually eligible beneficiaries and incentivizing ACOs to provide coordinated care to these populations. We believe this policy encourages participation in the Shared Savings Program from ACOs that otherwise may not have considered entering the program, as 45 percent of the ACOs receiving the HEBA in 2025 would not have qualified for the prior savings adjustment or positive regional adjustments, and therefore would have had a less favorable benchmark, had they not received the HEBA. However, since finalizing this policy, we concluded that it would add clarity to rename the HEBA to "population adjustment," to more accurately reflect the nature of the adjustment, which accounts for the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. Accordingly, in the CY 2026 PFS proposed rule (90 FR 32690 through 32693) we proposed changes to the Shared Savings Program regulations to rename the adjustment.

This proposed change seeks to harmonize the adjustment's name with the naming convention used for the other adjustments—the regional and prior savings adjustments—where the titles explicitly reflect key aspects of their underlying methodology. The adoption of the term "population adjustment" would reflect the specific data inputs and population focus of this adjustment, while also promoting consistency in nomenclature across adjustments.

As we explained in the CY 2026 PFS proposed rule (90 FR 32690), the proposed revisions to rename the HEBA differ from the approach proposed in the amendments to the Health Equity Adjustment applied to an ACO's quality score as described elsewhere in the proposed rule (90 FR 32677 through 32679). However, the intent and effect of these respective sections are distinct and therefore the proposed revisions reflect a separate rationale and methodology. Accordingly, the two sections serve different purposes and warrant distinct treatment within the rule.

b. Revisions to the Terminology in the Shared Savings Program Regulations Used to Describe the Adjustment

(1) Background

(a) Context for the HEBA

In the CY 2026 PFS proposed rule (90 FR 32690 and 32691), we stated that, relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we finalized the health equity adjustment to the historical benchmark for agreement periods beginning on January 1, 2025, and in subsequent years (89 FR 98155 through 98166). We finalized provisions of the regulation in 42 CFR part 425, subpart G (see §§ 425.652(a)(8) and 425.662) specifying the methodology for calculating the health equity adjustment to the historical benchmark, determining an ACO's eligibility for the adjustment, and the applicability of the adjustment. The text included the terms "health equity benchmark adjustment," "Health Equity Benchmark Adjustment (HEBA) scaler," and "HEBA." In the CY 2025 PFS final rule, we noted the limitations of benchmarks based on historically observed spending, as they could be set too low if they are based on the spending of a population of underserved communities. We discussed that without appropriate adjustments, ACOs caring for these populations may face financial penalties even if they succeed in improving access to high-value care during their agreement periods. Additionally, we noted that the Congressional Budget Office (CBO) reported high start-up costs for providers in rural and

underserved communities as a barrier to forming ACOs.[422] We stated in the CY 2025 PFS proposed rule that these providers may want to participate in ACOs but are disincentivized due to steep start-up costs. The HEBA was finalized to provide additional financial resources to ACOs serving these populations, and to encourage those ACOs to attract and retain beneficiaries from communities that have faced challenges accessing care. The adjustment is calculated based on the number of beneficiaries an ACO serves who are either enrolled in the LIS program or are dually eligible for Medicare and Medicaid, offering a targeted mechanism to reflect the needs of higher-risk populations.

(b) HEBA Provisions Finalized in CY 2025 PFS Final Rule

In the CY 2026 PFS proposed rule (90 FR 32691 and 32692), we stated that for agreement periods beginning on January 1, 2025, and in subsequent years, the Shared Savings Program utilizes three key mechanisms to upwardly adjust ACO benchmarks: the HEBA, the positive regional adjustment, and the prior savings adjustment. The positive regional adjustment evaluates an ACO's efficiency compared to its regional service area. The prior savings adjustment reflects an ACO's historical success in reducing Medicare fee-for-service (FFS) spending growth. The HEBA can increase benchmarks for ACOs with 15 percent or more assigned beneficiaries enrolled in LIS or dually eligible for Medicare/Medicaid, offering a targeted mechanism to reflect the needs of higher-risk populations.

These adjustments are not cumulative: ACOs receive the highest applicable adjustment, capped at 5 percent of national FFS per capita expenditures (89 FR 98158). For ACOs serving medically complex and high-cost beneficiaries, the HEBA often becomes their most favorable adjustment as they may not qualify for the regional adjustment or prior savings adjustments. While risk adjustment accounts for patient health status and dual eligibility status and benchmark calculations stratify expenditures by dual eligibility status, these mechanisms may fall short in fully reflecting costs for ACOs serving LIS or dually eligible beneficiaries in regions with high proportions of dual eligible and LIS populations. This can leave ACOs caring for these populations with unfavorable benchmarks and may reduce their incentive to participate in the program. As explained earlier in this section of this final rule, the HEBA addresses this gap by directly increasing benchmarks for ACOs with a significant proportion of LIS or dually eligible

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[422] Congressional Budget Office, "Medicare Accountable Care Organizations: Past Performance and Future Directions" (April 2024), available at https://www.cbo.gov/publication/59879.

beneficiaries, providing a meaningful financial incentive for participation by those ACOs and retention of such beneficiaries.

(c) HEBA Impact—Initial Observations

As described in the CY 2025 PFS final rule (89 FR 98158), CMS finalized a process to provide ACOs with a preliminary HEBA calculation at the start of their agreement period, using the ACO's BY3 assigned population. This preliminary calculation uses the proportion of the ACO's BY3 assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. We specified that we would then update the calculation when the ACO's historical benchmark is updated at the time of financial reconciliation for the performance year to reflect the ACO's performance year-assigned population in the calculation of the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

In the CY 2026 PFS proposed rule (90 FR 32691), we noted that based on internal analysis of PY 2025 preliminary benchmarks,[423] of 33 ACOs estimated to receive a HEBA, 13 are new ACOs participating in their first agreement period and would otherwise not have received a positive regional adjustment to the benchmark.

Following the publication of the CY 2026 PFS proposed rule, we have updated the values we have observed according to more updated data. Based on-internal analysis of PY 2025 final benchmarks, we note that among 16 ACOs estimated to receive a HEBA, 8 are new ACOs participating in their first agreement period and would otherwise not have received a positive regional adjustment to the benchmark (for example, ACO spending is above their region's expenditures) or a prior savings adjustment, since these ACOs are in their first agreement period. This later stage observation continues to suggest that the HEBA is encouraging more participation in the Shared Savings Program, as intended, by high-cost ACOs[424] that may otherwise not have elected to apply and participate in the program and whose assigned beneficiary populations have the greatest potential to benefit from care coordination and quality improvement. In the CY 2026 PFS proposed rule, we noted that our initial analysis of the preliminary benchmarks suggested that these ACOs could see an approximate 1.36 percent increase in their

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[423] These benchmarks are preliminary because they are established at the start of an ACO's agreement period and include incomplete data from benchmark year 3.

[424] By "high-cost ACOs," we refer in this rulemaking to those ACOs with spending above their region's expenditures.

benchmark compared to an approximate 2.29 percent for ACOs that received either a prior savings adjustment or positive regional adjustment (90 FR 32691). Analysis of the final benchmarks suggests that these ACOs could see an approximate 1.25 percent increase in their benchmark compared to an approximate 3.14 percent for ACOs that received either a prior savings adjustment or positive regional adjustment. Final information on the percentage of ACOs receiving the HEBA and the impact on their benchmarks will depend on the ACO's final PY 2025 assigned population, which is not determined until financial reconciliation, consistent with § 425.662(b)(4).

The Regulatory Impact Analysis of the HEBA from the CY 2025 PFS final rule (89 FR 98523 and 98524) estimated that total net savings is projected to grow over ten years by approximately $260 million as a result of the HEBA attracting additional high-cost ACOs to join the program and creating savings for the Medicare program, ranging from a $1.2 billion cost to a $2.2 billion savings at the 10th and 90th percentiles.

(d) Expanding Participation

In the CY 2026 PFS proposed rule (90 FR 32691 and 32692), we stated that the HEBA policy aligns with CMS' aims of advancing prevention, wellness, and chronic disease management, while supporting the growth and expansion of the Shared Savings Program. Analysis revealed significant untapped potential to increase Shared Savings Program participation among practices currently not participating in the program, in particular among providers serving higher cost populations.[425]

We conducted an analysis of Taxpayer Identification Numbers (TINs) associated with medical providers and/or practices not part of ACOs participating in the Shared Savings Program during PY 2022. The analysis compared TINs that participated in the Shared Savings Program with those that did not. Results indicated that many non-participating TINs served a larger share of beneficiaries with disabled or aged/dual enrollment status and had greater presence in rural areas. The study also found that of all the TINs serving beneficiaries eligible to participate in a Shared Savings Program ACO, 84 percent (or 58,000 TINs) were not participating in the Shared Savings Program. By contrast, only about 11,000 TINs with at least one ACO-assigned beneficiary participated in a Shared Savings Program ACO. Among these

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[425] CMS, Press Release "Dr. Mehmet Oz Shares Vision for CMS" (April 10, 2025), available at https://www.cms.gov/newsroom/press-releases/dr-mehmet-oz-shares-vision-cms.

non-participants, two-thirds were small practices that furnish care to 100 or fewer beneficiaries. The analysis also highlighted key differences between ACO participating and non-participating TINs in terms of the population they served and their geographic distribution. We observed that TINs associated with medical providers and/or practices not participating in Shared Savings Program ACOs are in regions with low Shared Savings Program ACO penetration and have a greater presence in rural areas. These practices serve larger shares of dual eligible and disabled beneficiaries and have higher spending per beneficiary driven primarily by inpatient and SNF expenditures.

Encouraging participation in ACOs by practices serving these higher-cost beneficiaries remain crucial to the Shared Savings Program. Our internal analysis shows that Shared Savings Program ACOs have been successful in reducing inpatient and SNF spending. The HEBA accounts for a higher proportion of dual eligible and LIS beneficiaries and therefore can strengthen the business case for providers that serve these populations to join and form ACOs and participate in the Shared Savings Program.

The adjustment is particularly critical in rural areas where the CBO has identified high start-up costs as a significant barrier to ACO formation.[426] By enabling ACOs in rural and resource-limited areas to operate under more viable and realistic financial benchmarks, the HEBA policy aims to expand participation in the Shared Savings Program and increase the likelihood that these ACOs can succeed financially while delivering high-quality care.

(2) Revisions

In the CY 2026 PFS proposed rule (90 FR 32692), we proposed to update the language used to describe the health equity adjustment to the benchmark to more accurately reflect the populations served by the ACOs receiving the adjustment. We noted that this change reflects efforts to harmonize terminology across benchmark-related methodologies—regional and prior savings adjustments—where the titles explicitly reflect key features of their underlying methodology. We further noted that the revision to "population adjustment" more accurately reflects the population of beneficiaries that are captured by this adjustment (ACOs' assigned beneficiaries who are enrolled in the Medicare Part D LIS

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[426] Congressional Budget Office, "Medicare Accountable Care Organizations: Past Performance and Future Directions" (April 2024), available at https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.

or dually eligible for Medicare and Medicaid), as well as promotes consistency in nomenclature across adjustment.

Specifically, we proposed to revise Shared Savings Program regulations that include references to "health equity benchmark adjustment" or HEBA to "population adjustment." We also proposed to revise the term "HEBA scaler," which is a component in the calculation to "scaler." The naming changes would apply for performance year 2025 and subsequent performance years. This proposal would revise only the terminology in the regulations. The calculation described in the regulations would be unchanged. We noted that this proposal, if finalized, would have a minimal impact on Shared Savings Program operations. CMS would only need to update the language used in historical benchmark reports and the assignment summary report, beginning with report deliveries occurring after the rule is finalized, and certain other programmatic materials, for example, the Medicare Shared Savings Program Assignment List Report and Assignment Summary Report User's Guide, and the Medicare Shared Savings Program's Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications.

These proposed revisions reflect changes to the terminology used in the regulations at §§ 425.652, 425.658, 425.662 and 425.672. We did not propose any changes in the methodology currently used to calculate the health equity benchmark adjustment. Specifically, we proposed the following revisions to provisions of the regulation (restated with minor corrections for clarity):

- At § 425.652(a)(8)(ii)(A), we proposed to remove the phrase "health equity benchmark adjustment (HEBA)" and add in its place the phrase "population adjustment."
- At § 425.652(a)(8)(ii)(B) introductory text, (a)(8)(ii)(B)(*2*), (a)(9)(v),and (a)(9)(vi), we proposed to remove the phrase "HEBA" and add in its place the phrase "population adjustment."
- At § 425.652(a)(9)(v), we proposed to remove the phrase "HEBA scaler used in calculating the HEBA under § 425.662(b)(2)" and add in its place the phrase "scaler used in calculating the population adjustment under § 425.662(b)(2)."
- At § 425.658(d), we proposed to remove the phrase "HEBA" and add in its place the phrase "population adjustment."
- At § 425.662, we proposed to revise the section heading to read as follows: "Calculating the population adjustment to the historical benchmark."

- At § 425.662 we proposed to revise paragraph (a) to read as follows: "*General*. For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates the population adjustment to the historical benchmark."

- At § 425.662(b) introductory text, we proposed to remove the phrase "health equity benchmark adjustment" and add in its place the phrase "population adjustment."

- At § 425.662(b)(2), and we proposed to remove the phrase "Calculates the HEBA scaler" and add in its place the phrase "Calculates a scaler."

- At § 425.662, we proposed to revise paragraph (b)(3) to read as follows: "Determines the ACO's eligibility for the population adjustment based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is only eligible for the population adjustment if this proportion is greater than or equal to 15 percent. An ACO with a proportion less than 15 percent is ineligible to receive the population adjustment."

- At § 425.662, we proposed to revise paragraph (b)(4) to read as follows: "Calculates the population adjustment. If the ACO is eligible for the population adjustment as determined in paragraph (b)(3) of this section, the adjustment is equal to the product of the scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid."

- At § 425.662, we proposed to revise paragraph (c) to read as follows: "*Applicability of the population adjustment.* CMS compares the population adjustment determined in paragraph (b)(4) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the per capita prior savings adjustment determined in § 425.658(c), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8)(ii)."

- At § 425.672 in paragraph (c)(2)(iv), we proposed to remove the phrase "and calculating the HEBA scaler" and add in its place the phrase "and calculating the scaler."

We sought public comments on these proposed changes. The following is a summary of comments received in response to our proposals and our responses.

Comment: Many commenters supported the proposed renaming of the "health equity benchmark

adjustment" to the "population adjustment." Some of these commenters agreed that the proposed renaming more accurately reflects the population of beneficiaries captured by the adjustment. Some of these commenters also supported the current HEBA methodology (which remains unchanged under the proposal), with some commenters noting the adjustment is important in recognizing upstream drivers or factors that impact beneficiary health outcomes, and the additional resources needed to provide care for underserved rural and urban patient populations. Some commenters noted that the population adjustment will encourage more participation in the program by high-cost ACOs.

Response: We thank commenters for their support.

Comment: A few commenters opposed the proposal and expressed disappointment over retraction of language and program facets related to health equity. A commenter noted that removing and/or disincentivizing policies to improve health equity and social determinants of health will have a detrimental effect on patients' health, leading to higher costs, while another commenter noted that the renaming withdraws recognition of health care providers who care for vulnerable patients. Another commenter supported the adjustment but mistakenly believed CMS proposed to sunset the HEBA. Another commenter, supportive of renaming the HEBA, suggested that CMS use an alternative name, the "Population and Income Adjustment and Bonus Points" (echoing phrasing used in the proposal to rename the Shared Savings Program's quality health equity adjustment, and seeming to mistake CMS' consideration of this phrasing for renaming the HEBA).

Response: We appreciate commenters' concerns and recommendations. We reaffirm that our intention is not to sunset an adjustment that could support improvements in patients' health or cost efficiencies, but rather to rename it. We note that the term "population adjustment" more accurately reflects the populations served by the ACOs who earn the adjustment (ACOs' assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid). We do not believe that renaming the adjustment withdraws recognition for health care providers who care for higher-risk populations as the methodology underlying the adjustment will not change and continues to encourage participation from and provide additional resources to ACOs serving high-cost, medically complex beneficiary populations. We disagree with commenters' recommendations for alternative names. We reiterate that, as noted in the CY 2026 PFS proposed rule, the renaming also harmonizes terminology

across benchmark-related methodologies—regional and prior savings adjustments—where the titles explicitly reflect key features of their underlying methodology (90 FR 32690).

Comment: A couple commenters, supportive of the proposed renaming, shared their belief that it is inconsistent to maintain the benchmark adjustment for finance-related policies for ACOs while simultaneously proposing to sunset the quality-related health equity adjustment, as both ensure that ACOs serving a disproportionate share of underserved beneficiaries are not disadvantaged in the Shared Savings Program.

Response: We acknowledge the comments regarding the differences between our proposal to rename (but maintain) the HEBA while proposing to remove the health equity adjustment, which is applicable to an ACO's quality score. We note that in the CY 2026 PFS proposed rule, CMS' proposal to sunset the health equity adjustment from the Shared Savings Program centers on the duplicative nature of this adjustment with other quality incentives and supports, specifically, the eCQM/MIPS CQM reporting incentive and the Complex Organization Adjustment (90 FR 32677 through 32679). In contrast, there are no Shared Savings Program financial benchmark adjustments that serve a similar function to the HEBA. Therefore, we believe it is appropriate to maintain the adjustment under the finance methodology. Additionally, we did not propose any changes in the methodology used to calculate the adjustment or substantive changes to the adjustment. We refer readers to section III.F.6.c(2) of this final rule for our responses to public comments on the proposal to sunset the health equity adjustment.

Many commenters shared feedback that went beyond the scope of our proposal to rename the adjustment, and we are not summarizing and responding to these comments in this final rule.

After consideration of public comments, we are finalizing our proposals to rename the "health equity benchmark adjustment" to the "population adjustment" and the "health equity benchmark adjustment scaler" to the "scaler" and make conforming revisions to the terminology used in the regulations at §§ 425.652, 425.658, 425.662 and 425.672. We are finalizing these changes as proposed with the following exception. In the CY 2026 PFS proposed rule (90 FR 32692, and 32859), we included somewhat duplicative proposed amendments to the phrasing in § 425.652(a)(9)(v). For clarity and to ensure accurate implementation of the amendments in the regulations: (1) we are finalizing our proposal to remove from § 425.652(a)(9)(v) the phrase "HEBA scaler used in calculating the HEBA under §

425.662(b)(2)" and add in its place the phrase "scaler used in calculating the population adjustment under § 425.662(b)(2)"; and (2) we are not finalizing our proposal to remove from § 425.652(a)(9)(v) the phrase "HEBA" and add in its place the phrase "population adjustment."

9. Shared Savings Program Quality Reporting Monitoring Provisions

a. Overview

In the CY 2026 PFS proposed rule (90 FR 32692 through 32694), we proposed to revise our regulations at § 425.316(c)(2) related to monitoring of ACOs for compliance with the quality performance standards. Relatedly, we proposed to revise § 425.224(b)(1)(ii)(A) related to reviewing applications for renewing and re-entering ACOs. We explained that the purpose of these proposed changes is to revise our regulations to ensure that ACOs continue to satisfy program requirements or to identify a pattern of noncompliance with ACOs meeting both the quality performance standard and the alternative quality performance standard. We stated our belief that these revisions would not significantly impact the program as currently implemented.

b. Background

In the CY 2021 PFS final rule (85 FR 84740 through 84743), we finalized changes to the Shared Savings Program quality performance standard and quality reporting requirements for performance years beginning on January 1, 2021. The regulation we finalized at § 425.316(c)(2) aligned the Shared Savings Program quality reporting requirements with the requirements that applied under the APP under the Quality Payment Program (85 FR 85039 and 85040). We have subsequently updated the quality performance standard and reporting requirements through rulemaking in the CYs 2022, 2023, 2024, and 2025 PFS final rules (86 FR 65255 through 65272, 87 FR 69860 through 69863, 88 FR 79112 through 79114, and 89 FR 98101 through 98132, respectively).

In the CY 2023 PFS final rule (87 FR 70234), we finalized an alternative quality performance standard at § 425.512(a)(4)(ii) and (a)(5)(ii) for performance year 2023 and subsequent performance years. Specifically, to meet the alternative quality performance standard for performance year 2025 and subsequent years as described at § 425.512(a)(5)(ii)(B), an ACO must report quality data on the APP Plus quality measure set established at § 414.1367 according to the method of submission established by CMS and achieve a quality performance score equivalent to or higher than the 10th percentile of the

performance benchmark on at least one of the outcome measures in the APP Plus quality measure set. An ACO that does not meet the quality performance standard but does meet the alternative quality performance standard is eligible to share in savings on a sliding scale as described at §§ 425.605 and 425.610. Additionally, ACOs that do not meet both the quality performance standard and the alternative quality performance standard are not eligible for shared savings and will have a shared loss rate not exceeding 75 percent as described at § 425.610(f)(3)(ii) for performance year 2023 and subsequent performance years.

The PHE for COVID-19 was in effect starting in January 2020 and expired on May 11, 2023.[427] All Shared Savings Program ACOs were deemed affected by the PHE for COVID-19 under the program's quality EUC policy for performance years 2022 and 2023 as defined at § 425.512(c) and were determined to have met the quality performance standard at § 425.512(a) (85 FR 84746). ACOs received a minimum quality performance score equal to the 30th percentile Merit-based Incentive Payment System (MIPS) Quality performance category score in PY 2022, and a score equal to the equivalent of the 40th percentile in PY 2023 across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. ACOs that were able to successfully report quality data received the higher of their own MIPS Quality performance category score (adjusted for health equity for performance year 2023, if applicable) or the applicable 30th percentile score. As such, all ACOs that qualified for shared savings for performance years 2022 and 2023 were eligible to receive the maximum sharing rate for their track (or performance level within a track) and, for performance year 2022, any shared losses determined to be owed to CMS using either a fixed (BASIC track) or scaled loss rate (ENHANCED track) were fully offset by the EUC policy and any shared losses determined for performance year 2023 were reduced by a least five-twelfths.

To ensure that the ACO continues to satisfy Shared Savings Program requirements, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers. The monitoring policies at § 425.316(c) apply to compliance with quality performance standards. To

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[427] *See* Administration for Strategic Preparedness & Response website, Declarations of a Public Health Emergency webpage, at https://aspr.hhs.gov/legal/PHE/pages/default.aspx (listing declarations of a public health emergency, among other information). *See also* U.S. Department of Health and Human Services website, COVID-19 Public Health Emergency webpage, available at https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.

identify ACOs that are not meeting the quality performance standards, we will review an ACO's submission of quality measurement data at §§ 425.500 or 425.512. Currently, as specified at § 425.316(c)(2)(i), if the ACO fails to meet the quality performance standard, we may take one or more of the actions prior to termination specified at § 425.216. As further specified at § 425.316(c)(2)(i), depending on the nature and severity of the noncompliance, we may forgo pre-termination actions and may immediately terminate the ACO's participation agreement at § 425.218. While § 425.316(c)(2) addresses the quality performance standard, it failed to acknowledge the alternative quality performance standard. When we established the alternative quality performance standard in the CY 2023 PFS final rule, we inadvertently did not also propose to modify the corresponding monitoring policies at § 425.316(c)(2). Due to the quality EUC policies in effect until 2023, we did not encounter this discrepancy when monitoring ACO compliance with quality performance standards.

c. Revisions

In the CY 2026 PFS proposed rule (90 FR 32693 through 32694), we proposed to add § 425.316(c)(3) to apply to performance years beginning on or after January 1, 2026. Further, the text of the proposed regulation in the CY 2026 PFS proposed rule (90 FR 32854) included a proposed revision to the introductory text of § 425.316(c)(2), to limit the applicability of this provision to performance years beginning on or after January 1, 2021 and before January 1, 2026, that was not described in preamble. Although the proposal was accidentally omitted from the preamble, this revision was proposed in the proposed regulatory text and we are finalizing as proposed. Under our proposal, if an ACO fails to meet both the quality performance standard and the alternative quality performance standard, as determined at § 425.512, we would be authorized to take one or more of the actions prior to termination as specified at § 425.216. Under the proposal, if an ACO is unable to meet the quality performance standard, then the ACO could still meet the alternative quality performance standard without CMS taking one of the prescribed actions prior to termination. We explained our belief that if an ACO fails to meet both standards, it would be appropriate for CMS to take one of the actions described at § 425.216 (provide a warning notice to the ACO, request a corrective action plan from the ACO, or place the ACO on a special monitoring plan) for noncompliance with the quality performance standards. We explained that we inadvertently did not modify the monitoring portion of the regulation, § 425.316(c), when we established

the alternative quality performance standard in the CY 2023 PFS final rule, and stated our belief that it would be appropriate to revise the regulation at § 425.316(c) to be consistent with our longstanding practice to monitor ACOs for their compliance with our quality reporting and quality performance standard requirements. Specifically, we proposed to add a new paragraph (c)(3) to § 425.316 to recognize that, for performance years beginning on or after January 1, 2026, if an ACO fails to meet both the quality performance standard and the alternative quality performance standard, as determined at § 425.512, CMS may take one or more of the actions prior to termination specified at § 425.216. Additionally, in keeping with our established policies at § 425.316(c)(2)(ii), we proposed to continue to terminate an ACO's participation agreement if it: (1) fails to meet both the quality performance standard and alternative quality performance standard for 2 consecutive PYs within an agreement period; (2) fails to meet both the quality performance standard and alternative quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order; (3) are a renewing ACO or re-entering ACO that fails to meet both the quality performance standard and alternative quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period; or (4) are a renewing ACO or re-entering ACO fails to meet both the quality performance standard and alternative quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

As part of the Shared Savings Program application process, we identify applicant ACOs that have previously participated in the Shared Savings Program. If the applicant ACO has a history of noncompliance with the requirements of the Shared Savings Program, we may request the ACO demonstrate that it has corrected the deficiencies that caused any noncompliance under their previous participation agreement (§ 425.224(b)(1)(iii)). The list of criteria we review for previous noncompliance includes, but is not limited to, whether the ACO demonstrated a pattern of failure to meet the quality performance standards, whether, for 2 PYs, the average per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiary population exceeded its updated benchmark, whether the

ACO failed to repay shared losses in full within 90 days, and whether the ACO failed to repay shared losses for any performance year while participating under a model authorized under section 1115A of the Act. In alignment with our proposed revisions to § 425.316(c), we also proposed to modify § 425.224(b)(1)(ii)(A) to include the alternative quality performance standard. Specifically, we proposed to modify § 425.224(b)(1)(ii)(A) to state that, as part of the factors we evaluate when determining whether to approve a renewing ACO's or re-entering ACO's application, we will evaluate whether the ACO demonstrated a pattern of failure to meet the quality performance standard and alternative quality performance standard (if applicable), or met any of the criteria for termination at § 425.316(c)(1)(ii), (c)(2)(ii), or (c)(3)(ii).

We solicited comments on these proposals.

We received a public comment on these proposals summarized below.

Comment: A commenter who opposed to the proposal stated that they objected to an ACO's termination from the Shared Savings Program for failure to meet quality performance standards in more than one performance year, as described under § 425.316(c)(3)(ii), and suggested instead that a termination be decided on a case-by-case basis.

Response: The Shared Savings Program seeks to both improve quality performance and reward high quality, while reducing the growth in Medicare spending. As we explained in the CY 2021 PFS final rule (see 85 FR 84743), in which we finalized the existing requirements under § 425.316(c), and we continue to believe, requirements for enforcing compliance with the quality performance standard help to hold ACOs accountable for the quality of the care they furnish to their beneficiaries and further encourage ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year. As we explained in the CY 2021 PFS final rule (85 FR 84743), in which we finalized the existing requirements under § 425.316(c), and we continue to believe, requirements for enforcing compliance with the quality performance standard help to hold ACOs accountable for the quality of the care they furnish to their beneficiaries and further encourage ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year. We believe these important objectives would continue to be further reinforced under the proposed

revisions to the Shared Savings Program requirements allowing for CMS to take compliance action when an ACO fails to meet the quality performance standard and the alternative quality performance standard.

The commenter appears to have misunderstood the intent of the proposal. Our intent is to only add a reference to the alternative quality performance standard, but it is not to modify the operations of the existing monitoring policy. Under the proposed approach, we would apply the existing requirements under § 425.316(c)(2) for performance years beginning on or after January 1, 2021 and before January 1, 2026; and we would apply the new requirements under new § 425.316(c)(3), for performance years beginning on or after January 1, 2026.

After consideration of a public comment received, we are finalizing as proposed to add new § 425.316(c)(3) with quality reporting monitoring requirements that will apply for performance years beginning on or after January 1, 2026. In accordance with§ 425.316(c)(3)(i), if an ACO fails to meet both the quality performance standard and the alternative quality performance standard, CMS may take one or more of the actions prior to termination specified at § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination and may immediately terminate the ACO's participation agreement under § 425.218. Specifically, in new § 425.316(c)(3)(ii)(A), CMS may terminate an ACO's participation agreement if the ACO fails to meet both the quality performance standard and the alternative quality performance standard for 2 consecutive years within an agreement period. In new § 425.316(c)(3)(ii)(B), CMS may terminate an ACO's participation agreement if the ACO fails to meet both the quality performance standard and the alternative quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order. Additionally, in new § 425.316(c)(3)(ii)(C), CMS may terminate an ACO's participation agreement for a renewing ACO or re-entering ACO if the ACO fails to meet both the quality performance standard and the alternative quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period. Lastly, under new § 425.316(c)(3)(ii)(D), CMS may terminate an ACO's participation agreement for a renewing ACO or re-entering if the ACO fails to meet both the quality performance standard and the alternative quality performance standard for 2 consecutive performance

years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

Further, the text of the proposed regulation in the CY 2026 PFS proposed rule (90 FR 32854) included a proposed revision to the introductory text of § 425.316(c)(2), to limit the applicability of this provision to performance years beginning on or after January 1, 2021 and before January 1, 2026, that was not described in preamble. This change is necessary so that we can effectuate the new § 425.316(c)(3) as explained in the proposed rule and its regulatory text to apply for performance years beginning on or after January 1, 2026. We received no comments addressing the proposed revision to § 425.316(c)(2) introductory text, and we are finalizing this change without modification.

We did not receive any public comments on our proposal to amend § 425.224(b)(1)(ii)(A) to include the alternative quality performance standard. We are finalizing our proposal, without modification, to revise § 425.224(b)(1)(ii)(A) to state that, as part of the factors we evaluate when determining whether to approve a renewing ACO's or re-entering ACO's application, we will evaluate whether the ACO demonstrated a pattern of failure to meet the quality performance standard and alternative quality performance standard (if applicable), or met any of the criteria for termination at § 425.316(c)(1)(ii), (c)(2)(ii), or (c)(3)(ii).

G. Changes to the Regulations Associated with the Ambulance Fee Schedule

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. (For a discussion about the ambulance inflation factor (AIF), please see CY 2011 PFS final rule (75 FR 73397). We stated in the CY 2011 PFS final rule that the AIF will be announced by instruction and on the CMS Web site. AIF transmittals are available on CMS' website*:* https://www.cms.gov/medicare/payment/fee-schedules/ambulance/afs-regulations-and-notices and in the Medicare Claims Processing Manual, Chapter 15, section 20.4). The AFS also incorporates two permanent add-on payments at § 414.610(c)(5)(i) and three temporary add-on payments at § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted July 15, 2009), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural

census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Section 3203 of the American Relief Act of 2025 (Pub. L. 118-158, December 21, 2024) extended these provisions through March 31, 2025. Most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119-4, March 15, 2025) amended section 1834(l)(13) of the Act to extend the payment add-ons through September 30, 2025. Thus, these payment add-ons apply to covered ground ambulance transports furnished before October 1, 2025. We proposed to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072), the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682), and the CY 2024 PFS final rule with comment period (88 FR 79292-79293)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary.

We received a comment regarding this proposal. The following is the summary of this comment we received and our response.

Comment: A commenter supported the proposal and agreed with CMS that the statutory provision is self-implementing and that these provisions are essential to protect access to vital emergency and non-emergency medical care.

Response: We appreciate the commenter's support of these provisions.

After consideration of the public comment that we received, we are finalizing our proposal to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010,

for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004, interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a "qualified rural area," that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the "Super Rural Bonus" and the qualified rural areas (also known as "super rural" areas) are identified during the claims process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Section 3203 of the American Relief Act of 2025 extended this provision through March 31, 2025. Most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through September 30, 2025. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before October 1, 2025, where transportation originates in a qualified rural area. Accordingly, we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072), the CY 2019 PFS final rule with comment period (83 FR 59682) and the CY 2024 PFS final rule with comment period (88 FR 79293)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through September 30, 2025, and does not require any substantive exercise of discretion on the part of the Secretary.

We received a few comments regarding this proposal. The following is the summary of the comments we received and our response.

Comment: A commenter supported the proposal and agreed with CMS that the statutory provision is self-implementing and that these provisions are essential to protect access to vital emergency and non-emergency medical care. Another commenter supported the proposal and stated that the policy is essential for protecting rural communities and that rural ambulance providers rely on this add-on payment as they often do not have an adequate patient volume to remain in business.

Response: We appreciate the commenters' support of these provisions.

After consideration of the public comments that we received, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

IV. Updates to the Quality Payment Program

A. CY 2026 Modifications to the Quality Payment Program Reporting and Data Submission

1. Executive Summary

a. Overview

This section of this final rule outlines changes to the Quality Payment Program starting January 1, 2026, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on alignment between the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APM) tracks of participation, alignment with broader CMS initiatives, and new options for clinicians to participate in more meaningful ways. We aim to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the MIPS and Advanced APMs for the CY 2026 performance period/2028 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, April 16, 2015), the Quality Payment Program is a value-based payment program, by which the Medicare program rewards clinicians who provide high-value, high-quality care to their patients in a cost-efficient manner. There are two ways for clinicians who provide services under the Medicare program to participate in the Quality Payment Program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined at § 414.1305)[428] are subject to a MIPS payment adjustment (positive, neutral, or negative) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to established performance standards for the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a "final score" as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance

[428] We note that the term MIPS eligible clinician is defined at § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. We refer readers to our policies governing group reporting and scoring under MIPS as set forth at § 414.1310(e).

categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight under these exceptions, for the CY 2026 performance period/2028 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment factor for a MIPS eligible clinician, CMS accounts for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act. CMS then applies the MIPS payment adjustment factor to amounts otherwise paid under Medicare Part B for covered professional services for the MIPS eligible clinician for the applicable MIPS payment year such that their payments for such covered professional services are increased, decreased, or not adjusted based on the MIPS eligible clinician's final score relative to the performance threshold.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

For the Advanced APM track, if an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to participate in MIPS and be subject to the MIPS reporting requirements and payment adjustment). Under current law, eligible clinicians who are QPs for the 2024 performance period and beyond will receive an increased physician fee schedule update of 0.75 percent based on the QP conversion factor in

the corresponding payment year. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year. We note that, historically, QPs received a lump sum APM Incentive Payment in the corresponding payment year, calculated as a specified percentage of the QP's paid claims for covered professional services from the base year. Under current law, payment year 2026 is the last year for these payments. Only legislation enacted by Congress can make changes to either the enhanced QP conversion factor updates or the APM Incentive Payment.

Active participation (or engaged clinicians) in the Quality Payment Program's MIPS track is defined as MIPS eligible clinicians who submitted at least one measure, attestation, or activity, or had this data submitted on their behalf. The percent of active participation has increased slightly to 94.02 percent in the eighth year (CY 2024 performance period/2026 MIPS payment year), with 488,937 engaged MIPS eligible clinicians out of 520,012 total MIPS eligible clinicians (defined as those who received a MIPS final score). In the CY 2023 performance period/2025 MIPS payment year, 93.97 percent of MIPS eligible clinicians actively participated in MIPS, with 508,790 engaged MIPS eligible clinicians out of 541,421 total MIPS eligible clinicians. Therefore, the active participation rate in MIPS increased slightly between the CY 2023 and CY 2024 performance periods. In addition, 87.37 percent of MIPS eligible clinicians will receive a positive payment adjustment for the 2026 MIPS payment year based on their performance in the CY 2024 performance period. Please note that results for the CY 2024 performance period/2026 MIPS payment year described herein are subject to change as a result of the targeted review process, which began on September 9, 2025, and concludes 30 days after the release of MIPS payment adjustments. For more information on the targeted review process for the CY 2024 performance period/2026 MIPS payment year, please see our targeted review guide at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3264/2024-Targeted-Review-User-Guide.pdf.

Regarding performance in Advanced APMs, for the CY 2024 QP Performance Period, 528,827 eligible clinicians (TIN– NPIs) earned Qualifying APM Participant (QP) status, while another 2,013 eligible clinicians earned partial QP status.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We continue to implement MIPS Value Pathways (MVPs) to allow for a more cohesive participation

experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the ninth year of the Quality Payment Program, we will be implementing the updates set forth in this section of this final rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

b. Summary of Major Proposals

(1) Transforming the Quality Payment Program

We continue to align with broader CMS initiatives, such as the Universal Foundation (*https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation*) in an effort to promote the highest quality outcomes and safest care for all individuals. The Universal Foundation focuses on provider attention, reducing burden, prioritizing development and movement toward interoperable digital quality measures, allowing for comparisons across CMS programs, and helping to identify measurement gaps.

We are implementing meaningful improvements designed to strengthen healthcare delivery and advance patient outcomes. Through these efforts, we strive to create a healthcare system that not only responds to chronic disease but works proactively to prevent it. In alignment with our goal of promoting preventive care and fostering a more proactive approach to health management, we are finalizing a new "Advancing Health and Wellness" subcategory within the improvement activities performance category. Through the policies described in this final rule, we intend to transform and simplify MIPS, promote the use of connected measures and activities, continue rewarding clinicians for providing high value care, and use data-driven information to help all clinicians improve care and engage patients.

Separately, we are expanding our portfolio of available MVPs for the CY 2026 performance period/2028 MIPS payment year and remain committed to our goal of ensuring more meaningful participation in the Quality Payment Program through MVPs. We revised the format of each MVP to categorize the quality measures by clinical conditions or episodes of care. The new format offers a streamlined set of quality measures to aid clinicians in selecting the most clinically relevant measures. While traditional MIPS continues to be a reporting option, we intend to end traditional MIPS in the

future, at which point MVPs would become mandatory. That future date has not been determined and will be established through the official notice and comment rulemaking process.

(a) Transforming MIPS: MVP Strategy

To support our goal of phasing out traditional MIPS and transitioning to MVP reporting, we are finalizing policies that will encourage increased participation from specialists. Our policies seek to specify which groups fall under the multispecialty subgroups requirement that begins in CY 2026 through self-attestation and to maintain flexibility for multispecialty small practices to report MVPs as groups. Specifically, we are finalizing updates to two MVP subgroup policies as follows: (1) update the MVP group registration process to add the specialty self-attestation requirement; and (2) maintain the MVP group reporting option for multispecialty groups with a small practice designation.

We also solicited feedback via three RFIs related to MVPs to address: (1) potential Core Elements MVP reporting requirements; and (2) functions utilizing Medicare procedural codes to further facilitate more MVP specialty reporting. Additionally, we solicited feedback on the future use of well-being and nutrition measures in the Quality Payment Program. We appreciate the feedback received on these requests for information which may inform future rulemaking.

(b) MIPS Value Pathways Development and Maintenance

To continue moving the healthcare community toward value-based, high-quality, safe, and cost-efficient care, we are finalizing six new MVPs around the following topics: Diagnostic Radiology, Interventional Radiology, Neuropsychology, Pathology, Podiatry, and Vascular Surgery.

We are also finalizing MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria and take into consideration feedback from interested parties we have received through the maintenance process. Additionally, we updated the format of the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP identified as “Clinical Groupings”.

Finally, we are finalizing our proposal to provide additional flexibilities to allow qualified clinical data registries (QCDRs) and qualified registries additional time to fully support finalized MVPs. Specifically, we are finalizing our proposal to sunset the current requirement and modify § 414.1400(b)(1)(ii) to state that QCDRs and qualified registries must support MVPs that are applicable

to the MVP participant on whose behalf they submit MIPS data through CY 2025 performance period/2027 MIPS payment year. We are also finalizing our proposal to modify the requirement at § 414.1400(b)(1)(ii) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than 1 year after finalization of the MVP. We are finalizing our proposal to retain the remaining language currently set forth at § 414.1400(b)(1)(ii) without modification.

(c) APM Performance Pathway

We are finalizing our proposal to update some quality measures in the APM Performance Pathway (APP), original quality measure set and the APP Plus quality measure set to reflect our proposed changes to measures specified for the quality performance category as discussed in section IV.A.4.b. of this final rule.

(d) Fast Healthcare Interoperability Resources (FHIR) Request for Information

We want to engage interested parties, ahead of future policy decisions, on the timeline and measure development of FHIR-based eCQMs in quality reporting and payment programs. In this RFI, we provided updates on our activities since prior RFIs and solicited information from interested parties on a range of issues. We appreciate the feedback received on this RFI which may inform future rulemaking.

(e) MIPS Quality Performance Category

For the CY 2026 performance period/2028 MIPS payment year, we are finalizing our proposal to establish a measure set inventory of 190 MIPS quality measures, of which 187 are available in traditional MIPS and three are available only for utilization in MVPs.

The proposed measure removals focus on process measures, measures reaching extremely topped-out status or the end of the topped-out measure lifecycle, measures no longer aligned with clinical guidelines and measures the steward would no longer maintain. The measure additions focus on measuring outcomes and increasing the number of eCQMs. Substantive changes to measures would ensure the measures included in MIPS continue to be meaningful and drive improvements in quality of care.

Additionally, as discussed in section IV.A.4.d.(1).(b). of this final rule, we are revising the definition of a "high priority measure" to remove health equity.

(f) MIPS Cost Performance Category

We are finalizing our proposal to modify the Total Per Capita Cost (TPCC) measure beginning in the CY 2026 performance period/2028 MIPS payment year. We are also finalizing our proposal to update the operational list of care episodes and patient condition groups and codes to reflect coding changes identified through our annual maintenance process for MIPS cost measures. Lastly, we are finalizing our proposal to adopt a 2-year informational-only feedback period for new MIPS cost measures, which we are also codifying at § 414.1380(b)(2).

(g) MIPS Improvement Activities Performance Category

We are finalizing the following updates to the MIPS Improvement Activity Inventory beginning with the CY 2026 performance period/2028 MIPS payment year. First, we are finalizing our proposal to add a new subcategory to the Improvement Activities performance category: Advancing Health and Wellness. Second, we are finalizing our proposal to remove the Achieving Health Equity subcategory. Third, we are finalizing our proposal to add three new improvement activities into two of our existing subcategories: (1) Population Management; and (2) Patient Safety and Practice Assessment. Fourth, we are finalizing our proposal to modify seven existing improvement activities currently specified for the performance category. Fifth, we are finalizing our proposal to remove eight improvement activities currently specified for the performance category.

(h) MIPS Promoting Interoperability Performance Category

Beginning with the CY 2026 performance period/2028 MIPS payment year, we are finalizing several policies and measure updates for the MIPS Promoting Interoperability performance category. Specifically, for the MIPS Promoting Interoperability performance category, we are finalizing the following proposals as proposed:

- Modification to the Security Risk Analysis measure;
- Modification to the High Priority Practices Safety Assurance Factors for Electronic Health Record (EHR) Resilience (SAFER) Guide measure; and

- Adoption of one new optional bonus measure, the Public Health Reporting Using Trusted Exchange Framework and Common Agreement™ (TEFCA™) measure.
- Amendment to rectify an incongruency in regulation at § 414.1380(b)(4)(ii)(C) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, the total number of bonus points available to be earned when reporting one bonus measure, more than one bonus measure, or all bonus measures is a total of five bonus points for the MIPS Promoting Interoperability performance category.

For the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, we are finalizing with modification the following proposals:

- Adoption of a measure suppression policy beginning with the CY 2026 performance period/2028 MIPS payment year and the EHR reporting period in CY 2026 that will not assess the performance of a suppressed measure and will allow MIPS eligible clinicians, eligible hospitals, and CAHs to receive the maximum available points for a measure or full credit for a measure; and
- Suppression of the Electronic Case Reporting measure for MIPS eligible clinicians for the CY 2025 performance period/2027 MIPS payment year and eligible hospitals and critical access hospitals for the EHR reporting period in CY 2025. MIPS eligible clinicians, eligible hospitals, and CAHs reporting the suppressed Electronic Case Reporting measure will be able to receive full credit for the measure under the Public Health and Clinical Data Exchange objective.

Additionally, in the CY 2026 PFS proposed rule (90 FR 32747 through 32751), we solicited public comment on the following RFIs:

- Query of Prescription Drug Monitoring Program (PDMP) Measure;
- RFI Regarding Performance-Based Measures; and
- RFI Regarding Data Quality.

We appreciate the feedback received on these RFIs, which may inform future rulemaking.

(i) MIPS Final Score Methodology (Scoring the Quality Performance Category)

We are finalizing our proposal to update our approach for identifying measures impacted by limited measure choice to apply the analysis and criteria finalized in the CY 2025 PFS final rule (89 FR 98432 and 98433) to MVPs, in addition to specialty measure sets. MVPs, similar to specialty measure

sets, contain a limited set of quality measures for a clinician to choose from. We are also finalizing our proposed list of topped-out measures impacted by limited measure choice and subject to the defined topped-out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

Lastly, we are finalizing our proposal to modify the methodology for scoring the administrative claims-based measures within the quality performance category beginning with the 2025 performance period/2027 MIPS payment year. The modification to the administrative claims-based quality measure scoring methodology will be based on standard deviation, median, and an achievement point value derived from the performance threshold.

(j) MIPS Payment Adjustment

We are finalizing our proposal to continue using the CY 2017 performance period/2019 MIPS payment year to establish a performance threshold of 75 points for the CY 2026 performance period/2028 MIPS payment year through the CY 2028 performance period/2030 MIPS payment year.

(k) Third Party Intermediaries

We are finalizing our proposal to codify at § 414.1400(d)(9) a policy we previously finalized in the CY 2025 PFS final rule to require CMS-approved survey vendors to submit a range of the cost of their services with their application beginning with the CY 2026 performance period/2028 MIPS payment year (89 FR 98459 and 98460). We are also finalizing our proposal to codify at § 414.1400(d)(3)(iv)(A) a policy previously finalized in the CY 2024 PFS final rule to require an entity to administer the CAHPS for MIPS Survey Spanish translation to Spanish-preferring patients (88 FR 79332 through 79334).

We are finalizing our proposal to require that, beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. We are finalizing our proposal to codify this requirement at § 414.1400(d)(10). In addition, we are finalizing our proposal to modify the requirements at § 414.1400(d)(3) for an entity applying to become a CMS-approved survey vendor to ensure the entity is capable of administering a web-mail-phone protocol prior to CMS approval. Lastly, we are finalizing our proposal to sunset one of the requirements to apply to become a CMS-approved survey vendor at § 414.1400(d)(8).

(2) Advanced APM Proposals

We are finalizing our proposal to modify the methodology we use to calculate QP status at § 414.1425 to include an individual calculation for all eligible clinicians in Advanced APMs. Additionally, we are finalizing with modification, our proposal to use Covered Professional Services to identify beneficiaries, as described at § 414.1305 to define Covered professional service attribution-eligible beneficiaries and evaluation and management (E/M) attribution eligible beneficiaries in our calculations for all Advanced APMs.

We are finalizing our proposal to sunset our Advanced APM criterion at § 414.1415(c)(7), and § 414.1420, which currently sets a limit on the number of clinicians belonging to an APM Entity participating in a Medical Home Model.

We are also finalizing our proposal to modify the language at § 414.1455(b)(3)(ii) and §414.1455(b)(3)(vi) that establishes Targeted Review for QPs to ensure that the Targeted Review timeline described in such section is the same timeline as that established for MIPS Targeted Reviews specified at § 414.1385(a)(2) and § 414.1385(a)(5).

2. Definitions

At § 414.1305, we are finalizing our proposals to revise definitions of the following terms:

- High priority measure
- Attribution-eligible beneficiary
- Covered professional service attribution-eligible beneficiary
- E/M attribution eligible beneficiary
- Multispecialty group
- MVP Participant
- Single specialty group

These terms and definitions are discussed in detail in the relevant sections of this final rule.

3. Transforming the Quality Payment Program

Section 1848(q)(1)(D) of the Act requires that the Secretary establish and apply a process that includes features of the provisions of section 1848(m)(3)(C) of the Act for MIPS eligible clinicians in a group practice reporting for the quality performance category and provides that the Secretary may establish such a process for the other three MIPS performance categories. Section 1848(q)(1)(D)(ii) of the Act requires that the process we establish and apply under section 1848(q)(1)(D)(i) of the Act, to the extent practicable, must reflect the range of items and services provided by the MIPS eligible clinicians within the group practice. In accordance with the statute, in the CY 2022 PFS final rule, we finalized the MIPS Value Pathways (MVP) reporting option for MIPS eligible clinicians beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). To support CMS' goal of phasing out traditional MIPS and transitioning to MVP reporting, we are finalizing policies that will enable groups to self-identify their specialty composition and submit MVP data that appropriately reflects the diverse range of services provided by the clinicians within the group. These policies would also help groups in assessing whether they would need to participate as subgroups, based on the scope of care provided by the clinicians within a group. Additionally, the subgroup policies will continue the voluntary subgroup participation option for multispecialty group practices that qualify as small practices. Additionally, we solicited feedback on developing a subset of key quality measures within MVPs to better enable comparison of clinician performance and emphasize measures that reflect the core of a specialty. We also solicited feedback on the consideration to identify Medicare Part B procedural billing codes that align with each MVP, and to encourage, or potentially require, specialists to report the relevant MVP based on their use of the procedural billing codes.

a. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized the option for MIPS eligible clinicians to participate as subgroups for reporting MVPs beginning in the CY 2023 performance period/ 2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to regulations at §§ 414.1305, 414.1318, and 414.1365 and the CY 2022 PFS final rule (86 FR 65398 through 65405), the CY 2023 PFS final rule (87

FR 70038 through 70045), and the CY 2024 PFS final rule (88 FR 79323 through 79328) for additional details on previously finalized subgroup policies.

In the CY 2022 PFS final rule (86 FR 65392 through 65394), we finalized the definition of an MVP participant at § 414.1305. Beginning with the CY 2023 performance period/2025 MIPS payment year, an MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. We also finalized at § 414.1305 that, beginning with the CY 2026 performance period/2028 MIPS payment year, an MVP Participant means an individual MIPS eligible clinician, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories (86 FR 65392 through 65394). We excluded "multispecialty group" from the MVP participant definition beginning with the CY 2026 performance period/2028 MIPS payment year and replaced the term with "subgroup" to account for the requirement for multispecialty groups to divide into subgroups if they choose to report MVPs.

Under the MVP Participant definition codified at § 414.1305, multispecialty groups and single specialty groups may report as groups or choose to form subgroups to report MVPs for the CY 2023 performance period/2025 MIPS payment year through the CY 2025 performance period/ 2027 MIPS payment year. Beginning with the CY 2026 MIPS performance period/2028 MIPS payment year, multispecialty groups will no longer be able to report MVP as a single group. This will mean that if a multispecialty group would like to report an MVP, beginning with the CY 2026 MIPS performance period/2028 MIPS payment year, MIPS eligible clinicians in multispecialty groups must divide into and report as subgroup or report as an individual to report an MVP. Alternatively, MIPS eligible clinicians in multispecialty groups may continue to participate in traditional MIPS reporting. In the CY 2023 PFS final rule (87 FR 70038 through 70040), we finalized at § 414.1305 the definitions of a single specialty group and a multispecialty group. Specifically, a single specialty group means a group as defined at § 414.1305 consisting of one specialty type, as determined by CMS using Medicare Part B claims. A multispecialty group means a group as defined at § 414.1305 consisting of two or more specialty types, as determined by CMS using Medicare Part B claims.

In the CY 2022 PFS final rule (86 FR 65415 through 65418), we also established a registration process at § 414.1365(b) for clinicians who choose to participate in MVP reporting. Under this policy, an MVP participant must register between April 1 and November 30 of the applicable calendar year performance period, or a later date specified by CMS. An MVP participant that elects to report the CAHPS for MIPS Survey associated with an MVP must complete their registration by June 30 of the applicable performance period. Section 414.1365(b)(2)(i) further provides that the MVP participant must select an MVP they intend to report and may select an outcomes-based administrative claims measure if available in the selected MVP (86 FR 65416 through 65417). We refer readers to the CY 2022 PFS final rule (86 FR 65415 through 65418) for additional details on MVP and subgroup registration requirements.

In the CY 2026 PFS proposed rule (90 FR 32699 through 32701), we proposed to: (1) maintain the MVP group reporting option for multispecialty groups with a small practice designation; and (2) modify the MVP group registration process to add the self-attestation requirement.

(2) Maintain the MVP group reporting option for small practices

At § 414.1305, beginning with the CY 2019 performance period/2021 MIPS payment year, we define a small practice to mean a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. As discussed in section IV.A.3.a.(1) of this final rule, we previously finalized subgroup reporting requirements for multispecialty groups beginning in the CY 2026 performance period/2028 MIPS payment year (86 FR 39360). Under this policy, a multispecialty group designated as a small practice (with 15 or fewer eligible clinicians) will not be allowed to participate as a single group in MVP reporting. If clinicians in such groups would like to participate in MVP reporting, beginning in the CY 2026 performance period/2028 MIPS payment year, such groups will currently need to divide into subgroups. Alternatively, clinicians in these groups could participate as individuals in MVP reporting or continue to report at the group level in traditional MIPS reporting.

We acknowledged that, like large groups, small practices could be classified as a single specialty or multispecialty groups. However, we do not believe there are additional benefits to require a small practice of 15 or fewer clinicians to further divide into smaller subgroups as we anticipate that multiple subgroups within a small practice could choose to report the same set of measures within the same MVP. Historically, we have received feedback from MIPS eligible clinicians in small practices expressing

concerns regarding the lack of adequate resources for these clinicians to meet MIPS reporting requirements. Additionally, we are concerned that requiring small practices to divide into smaller subgroups could negatively impact small practices as the subgroups may not meet the established case minimums for the quality measures in the selected MVP, resulting in lower scores. We recognize the challenges for small group practices to allocate the resources needed to administer quality reporting requirements. We are concerned that if we require multispecialty groups that qualify as small practices to divide and report as subgroups, these practices will avoid participating in MVP reporting and continue to participate in traditional MIPS reporting. Based on the 2022 Quality Payment Program Experience Report (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2817/2022ExperienceReport.pdf*), there is a decrease in MIPS participation from clinicians in small practices from the CY 2021 performance period/2023 MIPS payment year to the CY 2022 performance period/2024 MIPS payment year. Given that we intend to sunset traditional MIPS in a future year, we want to adopt policies which would reduce barriers for small group practices to transition to MVP reporting. Therefore, it would be beneficial to continue the MVP group reporting option for small practices regardless of the specialty composition of the clinicians within the small practices.

For the above reasons, in the CY 2026 PFS proposed rule (90 FR 32698 through 32699) we proposed to modify the definition of an MVP participant at § 414.1305 to provide that multispecialty groups that meet the requirements of a small practice may be MVP participants. Because multispecialty groups that meet the requirements of a small practice would meet the definition of an MVP participant, they would, unlike other multispecialty groups, be permitted to report an MVP as a single group. Specifically, we proposed to modify the definition of an MVP participant at § 414.1305 to provide that, for the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. Under this proposal, to utilize the MVP reporting option, a multispecialty group that meets the requirements of a small practice would not be required to divide and report as subgroups, although it could still do so if it chooses.

We solicited comments on the above proposal to modify the MVP participant definition at

§ 414.1305 by adding the term "multispecialty group that meets the requirements of a small practice" to maintain the MVP group reporting option for groups with a small practice designation. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to revise the definition of an MVP participant allowing a multispecialty group that meets the requirements of a small practice to participate as a group in MVP reporting and stated their belief that it reduces the administrative burden on small practices while sustaining engagement in MVPs.

Response: We thank the commenters for their support.

Comment: Several commenters recommended extending the MVP group reporting flexibility available for multispecialty small practices to multispecialty groups with 16 or more clinicians. Specifically, the commenters suggested maintaining the MVP group reporting option for all multispecialty group practices. The commenters expressed concern that the challenges related to subgroup participation, such as increased reporting burden and difficulties in meeting the case minimums for quality measures exist for all multispecialty group practices, regardless of the group size.

Response: We appreciate the commenters' recommendation to extend the MVP group reporting flexibility to multispecialty group practices of all sizes and not just multispecialty small practices. We implemented subgroup reporting for MVPs based on consistent feedback received from multispecialty group practices recommending we offer a participation option for a multispecialty group practice to report MIPS measures and activities that comprehensively capture the diverse range of services provided by the clinicians in a group. While we are certain that the increased reporting associated with required subgroups will be beneficial to the public by allowing more reporting on specialists in multispecialty practices, we recognize the need to balance that against administrative burden for smaller practices with limited resources. We have previously adopted similar flexibilities exclusively for small practices, such as bonus points and reduced reporting requirements for small practices participating in MIPS due to limited resources and infrastructure support for clinicians in these practices. We anticipate that multispecialty group practices that do not meet the requirements of small practices may have the ability to select an MVP with relevant quality measures due to the expanded range of services provided by the clinicians within the group which would allow them to meet case minimums. Additionally, we anticipate that

clinicians in multispecialty groups that do not qualify as a small practice would benefit from participating as subgroups as it allows clinicians involved in multiple foci of care to report on the measures relevant to the scope of care provided. We refer readers to the CY 2022 PFS final rule (86 FR 65392 through 65394) for additional details on the discussion regarding the previously finalized MVP participant definition.

Comment: A commenter recommended CMS continue offering support for small practices and ensuring that the requirement excluding small practices does not impact the overall performance of small practices participating in MVP reporting. Another commenter requested CMS to monitor the implementation of this policy to ensure that it achieves its intended purpose of reducing reporting burden without compromising the validity of performance measurement.

Response: Under the proposed policy, multispecialty groups that qualify as small practices may continue to use the MVP group reporting option and may choose to participate as subgroups. As a result, we expect multispecialty small practices to choose their participation options, as an individual, group, or subgroup, in MVP reporting to align with their practice needs. Therefore, we do not anticipate negative impacts on MVP scores for small practices because of this policy. Clinicians may also seek support via the Quality Payment Program Help Desk at qpp@cms.hhs.gov. We will continue to monitor the effects of this policy on small practices for any unintended consequences and will provide additional support as needed.

After consideration of public comments, we are finalizing to modify the definition of an MVP participant at § 414.1305 as proposed to provide that, for the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. Under this policy, to utilize the MVP reporting option, a multispecialty group that meets the requirements of a small practice would not be required to divide and report as subgroups, although it could still do so if it chooses.

(3) Update the MVP Group Registration Process

Beginning in the CY 2026 performance period/2028 MIPS payment year, to implement the subgroup reporting requirement for multispecialty groups as previously discussed, we would need to

determine the specialty composition of a group as a single specialty or multispecialty group as defined at § 414.1305. Currently in the Quality Payment Program, we assign specialty type for MIPS eligible clinicians at the individual clinician (or TIN-NPI) level and not collectively at the group (or TIN) level. As discussed in the CY 2023 PFS final rule (87 FR 70039), we currently use the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and Medicare Part B claims data to identify clinician specialty for different purposes. For public reporting purposes, we rely on PECOS as the primary data source, and for purposes of MIPS eligibility determination, we use both PECOS and claims data. Additionally, we use the information on claims to identify clinician specialty when attributing some of the measures in the cost and quality performance categories.

As discussed above in section IV.A.3.a.(1) of this final rule, we finalized at § 414.1305 in the CY 2023 PFS final rule (87 FR 70038 through 70040) the definition of a single specialty group as a group consisting of one specialty type, and the definition of a multispecialty group as a group consisting of two or more specialty types, as determined by CMS using Medicare Part B claims. In the CY 2023 PFS final rule (87 FR 70039 through 70040), we received mixed feedback from commenters on the proposal to utilize claims data for identifying specialty composition of a group. Many were concerned that the specialty information indicated on Medicare Part B claims is not an accurate representation of the actual care provided by the various clinicians in a multispecialty group. A few commenters recommended the use of a specialty attestation process during subgroup registration instead of using the claims data. In responding to the comments received regarding the recommendation to consider a specialty attestation process, we explained our intent was to provide group specialty designations either as a single specialty or multispecialty group in advance of the MVP registration process, allowing group practices to make changes in their administrative workflows accordingly (87 FR70040).

To operationalize the previously finalized definitions of a single specialty and multispecialty group and to implement the previously finalized CY 2026 subgroup reporting requirement for multispecialty group practices, we considered utilizing claims data to assign these specialty designations to group practices. After further analyzing the claims data, we recognize and agree there are additional nuances to consider in using the claims analysis to accurately identify the specialty composition of a group.

For example, the claims data may not reflect the care provided by certain clinician types in a group, such as nurse practitioners (NPs), and physician assistants (PAs). The NPs and PAs that are part of group practices could be involved in more than one clinical focus and the specialty information on claims for these clinicians reflects their educational credentials rather than the type of care provided.

We recognize there could be instances when a group practice consists of clinicians across multiple specialty types but provides care in a single clinical area. We are also concerned that using the individual clinician (or NPI) level specialty code information available from the claims data to collectively designate a group as either a single specialty or multispecialty would inadvertently misrepresent the specialty composition of a group because of the way clinician specialty is reflected on claims. For example, claims data would indicate that a group practice, focused on providing cardiovascular care for patients and consisting of internists, cardiologists, NPs, and PAs, meets our definition of a multispecialty group. If we use claims data to implement the previously finalized definitions of single specialty and multispecialty groups, this group providing cardiovascular care would be designated as a multispecialty group and will be required to form subgroups for reporting an MVP beginning in the CY 2026 performance period/2028 MIPS payment year. Given the single clinical focus of care provided by all the clinicians in such group practice, we anticipate the multiple subgroups within such group would choose to report the measures and activities in the Advancing Care for Heart Disease MVP, resulting in redundant data submissions. In such instances, we acknowledge utilizing the claims data would result in CMS incorrectly identifying a group's specialty composition as a single specialty or a multispecialty group.

Additionally, we acknowledged that the composition of groups may not be constant due to several factors unrelated to MVP policies (for example, clinician turnover and acquisitions or consolidation of practices). In instances when the overall composition of a group changes due to clinician turnover, consolidation of practices, or other reasons, the specialty designations provided by CMS may not fully capture the changes in the group composition during a performance period. Therefore, we are unable to utilize the claims data at this time to evaluate the specialty composition of a group or to designate a group practice as either a single specialty or a multispecialty group. We recognize we need to conduct a thorough analysis of the claims data to pursue an effective and sophisticated approach for

assessing the feasibility of appropriately assigning specialty designations to groups. Please see our discussion in section IV.A.3.c. of this final rule for language associated with the Medicare Procedural Codes Request for Information (RFI), where we discuss potential alternative approaches for utilizing Medicare Part B claims to identify clinician specialties within a group for considering policies encouraging MIPS eligible clinicians to report an MVP aligned with the scope of care provided.

In lieu of using the claims data for designating a group as either a single specialty or a multispecialty group, we proposed that to report an MVP, a group practice which is either a single-specialty group or a multispecialty group that meets the requirements of a small practice, would be required to attest to its designation as a group that meets the requirements of a single specialty group, or a multispecialty group that meets the requirements of a small practice, respectively. We noted that we did not propose the self-attestation requirement for subgroups because under the current policy at § 414.1365(b), subgroup registration is an additional step in the MVP registration process for multispecialty groups choosing to report an MVP. We refer readers to the CY 2022 and CY 2023 PFS final rules (86 FR 65415 through 65418 and 87 FR 70040 through 70041) for previously finalized MVP subgroup registration requirements.

In the CY 2026 PFS proposed rule (90 FR 32699 through 32700), we proposed to expand the definition of MVP Participant to include multispecialty groups meeting the requirements of small practices. Under this proposal, a multispecialty group practice consisting of 15 or fewer clinicians that chooses to report an MVP would be exempt from the requirement to participate as subgroups. For a group practice consisting of 16 or more clinicians, and the clinicians within the group are involved in a single focus of care, we anticipated the group practice will attest as a single specialty group and register as a single group for MVP reporting. If a group practice consists of 16 or more clinicians and the clinicians within the group are involved in multiple foci of care, the group practice cannot register for MVP reporting as a single group. MIPS eligible clinicians in such groups would need to divide into subgroups or if applicable, participate as individuals for reporting an MVP.

To align with the proposed self-attestation process during MVP registration as a mechanism for identifying the group specialty composition, we proposed modifying the definitions of a single specialty group and a multispecialty group. These proposed updates and the self-attestation requirement for groups

participating in MVP reporting would enable group practices to assess their need for participation as subgroups based on the scope of care provided by the clinicians within the group. Additionally, the proposed updates would allow either a single-specialty group or a multispecialty group that meets the requirements of a small practice to self-identify themselves and report the MVP as a single group. This proposed process would also alleviate the concerns associated with determining a group's specialty composition due to inaccurate representation of the clinician specialty information on the claims data.

For the above reasons, to implement the previously finalized subgroup reporting requirement for multispecialty group practices beginning with CY 2026 performance period/2028 MIPS payment year and to operationalize the definitions of a single specialty and multispecialty group, in the CY 2026 PFS proposed rule (90 FR 32698 and 32699), we proposed updates to the previously finalized MVP registration process to include the addition of a self-attestation process for groups to identify themselves as either a single specialty group or a multispecialty group that meets the requirements of a small practice. Specifically, we proposed that, beginning with the CY 2026 performance period/2028 MIPS payment year, a group practice registering for MVP reporting that intends to participate as a single group will need to attest either as a single specialty group or a multispecialty group that meets the requirements of a small practice during MVP registration.

In the CY 2026 PFS proposed rule (90 FR 32701), we proposed to codify the proposal at § 414.1365(b)(2)(iv), providing that, beginning with the CY 2026 performance period/2028 MIPS payment year, to report an MVP, a group must attest to being either a single specialty group or a multispecialty group that meets the requirements of a small practice. As previously discussed, in this section of the final rule, we are unable to utilize claims data for designating a group as either a single specialty group or a multispecialty group. Therefore, we proposed to make conforming changes and revise the current definitions of a single specialty group and a multispecialty group at § 414.1305. We proposed to revise the definition of a single specialty group at § 414.1305 to mean a group that consists of clinicians in one specialty type or clinicians involved in a single focus of care. We proposed to revise the definition of a multispecialty group at § 414.1305 to mean a group that consists of clinicians in two or more specialty types or clinicians involved in multiple foci of care.

We solicited public comments on the proposal to update the MVP group registration by adding a

self-attestation requirement. We also solicited comments on conforming proposals to update the definitions of a single specialty group and a multispecialty group. We refer readers to section V.B.5.c.(6).(b). of this final rule for discussion on the burden estimates for these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed modification to the MVP group registration process, which would allow group practices to self-attest to their specialty composition and align MVP reporting accordingly. The commenters appreciated CMS acknowledging the limitations of utilizing PECOS and Medicare Part B claims data to designate a group as either a single specialty or a small multi-specialty group. Several commenters believe that the proposal promotes flexibility and reduces administrative burdens while enabling practices to more accurately represent their care delivery structure.

Response: We thank the commenters for their support.

Comment: A commenter recommended CMS implement the self-attestation process for groups of all sizes, and not just multispecialty groups that meet the requirements of a small practice, noting concerns that lack of a self-attestation process would require a multispecialty group to further divide into subgroups.

Response: We acknowledge the commenter's concern regarding implementing the self-attestation requirement only for multispecialty groups that meet the requirements of a small practice. We would like to clarify that the self-attestation process would be available for group practices of all sizes to self-identify whether they are considered as a single specialty or a multispecialty group. Under this policy finalized in section XX of this final rule, only group practices that attest as a single specialty group may register as a single group for reporting an MVP. Groups with 16 or more clinicians (that are not small practices) that do not attest as a single specialty group would be considered as a multispecialty group and would not be allowed to register as a single group for reporting an MVP. Such groups choosing to report an MVP would need to divide into subgroups or participate as individuals.

Comment: A few commenters recommended CMS implement additional safeguards for the specialty self-attestation process to avoid inaccurate specialty attestations and provide additional guidance on auditing and validating group self-attestation statements.

Response: We appreciate the commenters' recommendations to implement additional safeguards to prevent inaccurate use of the self-attestation process and to clarify auditing and validation requirements. We expect group practices to use the self-attestation process to accurately identify a group's specialty composition to the extent feasible. We also note that we will apply the existing data validation and auditing requirements described under § 414.1390 for auditing subgroups. We will also continue to monitor the use of the self-attestation process by groups and as needed, provide additional guidance specific to auditing and validating subgroups in the future.

Comment: A commenter recommended that in addition to the self-attestation process, CMS also consider specialty volume within a group practice that self-attests as a multispecialty group, allowing the group to report the MVP relevant to the predominant specialty instead of dividing into subgroups.

Response: We appreciate the commenter's recommendation to consider specialty volume within a group practice that self-attests as a multispecialty group and to allow group reporting of the MVP relevant to the predominant specialty. Under the proposed self-attestation process, a group consisting of clinicians across multiple specialty types would only need to attest as either a single specialty or a multispecialty group. We do not require groups attesting as a single specialty or a multispecialty to provide details on individual clinician specialties. Identifying the predominant specialty volume would require groups to submit additional information, such as clinician specialty type and the clinical area of care, which would increase the burden and complexity of the self-attestation process. Furthermore, the predominant specialty volume within a group practice may fluctuate due to changes in the groups' composition as a result of clinician turnover or practice mergers. We have not implemented stringent restrictions on the composition of a subgroup, allowing group practices to organize clinicians into subgroups based on the scope of care provided. For example, a multispecialty cardiology group practice, consisting of cardiologists and internists in which majority of the clinicians are cardiologists. The cardiologists in this group could form one subgroup to report the Advancing Care for Heart Disease MVP, while the internists could form a second subgroup or report as individuals.

Comment: A commenter did not support the proposed self-attestation process and stated their belief that it would increase administrative burden for clinicians and vendors.

Response: We acknowledge the commenter's concerns regarding the administrative burden for

clinicians and vendors associated with the proposed addition of the self-attestation requirement to the MVP group registration process. The self-attestation process will only require a multispecialty group practice to select whether they consider their group to be a single specialty group or a multispecialty group, adding no additional burden to the existing estimated burden for MVP registration. We refer readers to section XX of this final rule for additional details on the burden related to MVP registration. Furthermore, for multispecialty groups providing a single focus of care, the addition of self-attestation requirement will allow such groups to report an MVP as a group instead of dividing into subgroups.

Comment: Many commenters supported the proposed changes to the definitions of a single specialty and a multispecialty.

Response: We thank the commenters for their support.

Comment: Many commenters urged CMS to further clarify the proposed definitions and more accurately capture the intent of the proposal, ensuring the definitions are mutually exclusive and emphasizing the differences in the focus of care, thus ensuring multispecialty groups with a single focus of care would not need to form subgroups for reporting an MVP. Specifically, several commenters recommended that CMS make modifications to the proposed definitions to more accurately capture the emphasis on the focus of care rather than the distinct number of specialty types within a group. A few commenters requested CMS to issue subregulatory guidance for assisting group practices to apply the definitions during the self-attestation process.

Response: We appreciate the commenters' support for the proposed definitions of a single specialty and multispecialty group. We acknowledge the recommendations to further clarify the proposed definitions by emphasizing the focus of care provided by the clinicians in a group practice rather than the number of specialty type. We note that the intent of the proposed definitions is to emphasize the focus of care provided by the clinicians within a group, rather than the number of distinct specialty types. To further clarify, a group composed of clinicians with a single specialty type would attest as a single specialty group. Alternatively, a group with clinicians in two or more specialty types, who share a single focus of care, and not involved in multiple foci of care, would attest as a single specialty group and collectively participate as a group in MVP reporting. We will consider the commenters' recommendation to provide subregulatory guidance to assist group practices to apply these definitions and appropriately

identify their specialty composition. We will include additional guidance in educational resources and materials shared with clinicians and other interested parties participating in MVP reporting to further clarify the relevance of these to MVPs.

After consideration of public comments, we are finalizing the proposal at § 414.1365(b)(2)(iv) without modification, providing that, beginning with the CY 2026 performance period/2028 MIPS payment year, to report an MVP, a group must attest to being either a single specialty group or a multispecialty group that meets the requirements of a small practice. We are also finalizing the proposed conforming changes to revise the current definitions of a single specialty group and a multispecialty group at § 414.1305. We are finalizing, as proposed, to revise the definition of a single specialty group at § 414.1305 to mean a group that consists of clinicians in one specialty type or clinicians involved in a single focus of care. We are also finalizing, as proposed, to revise the definition of a multispecialty group at § 414.1305 to mean a group that consists of clinicians in two or more specialty types or clinicians involved in multiple foci of care.

b. Core Elements Request for Information (RFI)

One of the goals of the transition from traditional MIPS to MVPs is to provide patients with comparative clinician performance data to make better assessments of the care provided to patients by requiring clinicians within an MVP to report on the same group of measures. While MVPs were designed to reduce the burden of measure selection by narrowing the scope of large, unaligned inventories, some MVPs still have a large selection of measures to accommodate the variety of clinicians who may choose to report that MVP. The MVPs finalized for the CY 2025 performance period/2027 MIPS payment year contain an average of 14 quality measures for MVP Participants to select from, ranging from 8 to 24 quality measures in each MVP (89 FR 98972 through 99056). Given this degree of measure volume, we are concerned that MVP reporting may not produce sufficient comparative performance data on standardized measures to support patient choice of care.

We considered policies to ensure more direct comparability by requiring the reporting of a subset of measures within an MVP that are meaningful for clinicians and patients. In the CY 2026 PFS proposed rule (90 FR 32701 and 32702) we issued an RFI to solicit feedback on a policy to require an MVP Participant to report one of the four required quality measure from a subset of quality measures in each

MVP, referred to as "Core Elements," that reflect care that is at the crux of the MVP's applicable specialty, medical condition, or episode of care. Specifically, we requested feedback on alternative approaches to achieving the goals of the Core Elements policy, the ideal number of Core Elements in an MVP, appropriate measures and collection types for Core Elements, the timeline for proposing the Core Elements policy, and potential implications for MVP reporting. Please note, this was an RFI only. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

c. Medicare Procedural Codes Request for Information (RFI)

In the CY 2022 PFS final rule (86 FR 65392 through 65394), we finalized the MVP reporting option for MIPS eligible clinicians beginning in the CY 2023 performance period/2025 MIPS payment year. To advance our goal of phasing out traditional MIPS and fully transitioning to MVP reporting, we continue to develop and maintain MVPs that are meaningful and relevant to the clinicians currently participating in MIPS. For the CY 2025 performance period, there are 21 MVPs available, covering the services provided by a wide range of clinician specialty types. Based on internal data, we received over 2,000 MVP registrations (including groups, individual clinicians, and subgroups) for the CY 2024 performance period/2026 MIPS payment year. Exploring approaches to utilize Medicare procedural billing codes for appropriately identifying MVPs relevant to a clinician specialty type could further increase MVP participation, ensure that clinicians report an MVP that is relevant to their scope of care to make performance measurements more clinically relevant for specialists, and inform patient choice of care with meaningful and comparative clinician performance data.

In the CY 2026 PFS proposed rule (90 FR 32702 and 32703) we issued an RFI to solicit feedback on encouraging and potentially requiring specialists to report a relevant MVP based on their use of procedural billing codes from Medicare Part B claims data. Specifically, we solicited feedback on alternative approaches to encourage specialty reporting of relevant MVPs, the appropriate data sources, volume threshold, and determination period to assign clinicians to an MVP, and clinician readiness to report an MVP assigned according to Medicare Part B claims data. Please note, this was an RFI only. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

d. Well-being and Nutrition Measures Request for Information (RFI)

In the CY 2026 PFS proposed rule (90 FR 32703) we issued an RFI to solicit input on well-being and nutrition measures for future years in the QPP. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues.[429] This comprehensive approach emphasizes person-centered care by promoting the well-being of patients and family members. Specifically, we solicited comments on tools and measures that assess overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment; the applicability of tools and constructs that assess the integration of complementary and integrative health, skill building, and self-care; and relevant aspects of well-being for the Quality Payment Program. Please note, this was an RFI only. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

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[429] Well-Being Concepts. (2017). CDC Archives. Available at: *https://www.naspa.org/images/uploads/kcs/WHPL_Canon_WB_WellBeing_Concepts___HRQOL___CDC_2017.pdf.*

4. QPP Reporting and Data Submission

a. CY 2026 MVP Development and Maintenance

(1) Development of New MIPS Value Pathways (MVPs)

In the CY 2023 PFS final rule (87 FR 70035 through 70037), we finalized modifications to the MVP development process to broaden opportunities for the general public to provide feedback on new candidate MVPs prior to the notice and comment rulemaking process. We refer readers to the Quality Payment Program website to review the public feedback we received for each 2026 MVP candidate (*https://qpp.cms.gov/mips/candidate-feedback*).

Through our development processes for new MVPs (85 FR 84849 through 84856; 87 FR 70035 through 70037), we aim to gradually develop new MVPs that are relevant and meaningful for MIPS eligible clinicians. In the CY 2026 PFS proposed rule (90 FR 33182 through 33204), we proposed adopting the following six new MVPs:

- Diagnostic Radiology;
- Interventional Radiology;
- Neuropsychology;
- Pathology;
- Podiatry; and
- Vascular Surgery.

We refer readers to Appendix 3: MVP Inventory, of this final rule for discussion of the proposed new MVPs, the public comments received, and our responses.

We continue to encourage interested parties to utilize our established pre-rulemaking processes to develop and submit candidate quality and cost measures relevant to their specialty. Furthermore, we continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document (https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*),*

(2) MVP Maintenance Updates to Previously Finalized MVPs

Between the CY 2022 PFS final rule (86 FR 65998 through 66031) and the CY 2023 PFS final rule (87 FR 70037), we finalized the following 12 MVPs to be available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Advancing Cancer Care;
- Advancing Care for Heart Disease;
- Advancing Rheumatology Patient Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Improving Care for Lower Extremity Joint Repair;
- Optimizing Chronic Disease Management;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Patient Safety and Support of Positive Experiences with Anesthesia;
- Promoting Wellness; and
- Supportive Care for Cognitive-Based Neurological Conditions.

In the CY 2024 PFS final rule (88 FR 79978 through 80047), we consolidated Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single primary care MVP titled "Value in Primary Care MVP" as well as finalized the following five additional MVPs to be available for reporting beginning with the CY 2024 performance period/2026 MIPS payment year:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disorders Including Hepatitis C and Human Immunodeficiency Virus (HIV);
- Quality Care for the Treatment of Ear, Nose, and Throat Disorders;
- Quality Care in Mental Health and Substance Use Disorder; and
- Rehabilitative Support for Musculoskeletal Care.

In the CY 2025 PFS final rule (88 FR 79978 through 80047), we consolidated Optimal Care for Patients with Episodic Neurological Conditions and the Supportive Care for Neurodegenerative Conditions MVPs into a single neurological MVP titled "Quality Care for Patients

with Neurological Conditions MVP" as well as finalized the following six additional MVPs to be available for reporting beginning with the CY 2025 performance period/2027 MIPS payment year:

- Complete Ophthalmologic Care;
- Dermatological Care;
- Gastroenterology Care;
- Pulmonology Care; and
- Surgical Care.

In the CY 2026 PFS proposed rule (90 FR 33205 through 33257), we proposed modifications to all 21 previously finalized MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria we previously established (85 FR 84849 through 84854). Through these modifications, we can expand upon the clinical concepts, advance health and wellness, address maintenance requests from the public, and remove measures and activities that would either be finalized for removal from their respective MIPS Inventory or replaced by more robust measures or activities.

Additionally, we updated the format of the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP. The new format does not change the measures and activities included in the MVP. It is intended to provide a more user-friendly format for MIPS eligible clinicians when choosing the measures and activities most applicable to their practice.

We received public comments on these updates. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed concerns about the inconsistent inclusion of the "advancing health and wellness" and "experience of care" clinical groupings in MVPs and noted the rule did not clearly explain how these determinations were made.

Response: We updated the format of the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP to provide a more user-friendly format for MIPS eligible clinicians when choosing the measures and activities most applicable to their practice. As there are no reporting requirements based upon clinical groupings, the methodology for determining the structure and inclusion of each grouping was not explicitly stated. The Advancing Health and Wellness clinical

grouping represents an administration priority that should be in the forefront of all care. These measures represent broadly applicable concepts that would be relevant to all clinicians who may report the MVP and are important for the overall health and wellbeing of each patient. The Experience of Care bucket includes measures representing broadly applicable assessments capturing the patient voice, experience of care, and/or shared decision making that would be relevant to all clinicians who may report the MVP. Both the Advancing Health and Wellness and Experience of Care clinical groupings contain measures that, due to their broadly applicable nature, could be included in other clinical groupings within the MVP. However, for clarity, we chose to list each measure once using the clinical grouping that was the most appropriate based upon different factors, such as the MVP topic, targeted specialties/subspecialties, denominator eligible patient populations, and purpose of measure inclusion.

In addition, we received public comments on the proposed maintenance updates to previously finalized MVPs. We refer readers to Appendix 3: MVP Inventory of this final rule for the proposed modifications to the previously finalized MVPs, the public comments received, and our responses. We also refer readers to section V.B.5.c.(6)(a) of this final rule for discussion on the burden estimates for these proposals.

(3) Third Party Intermediaries Support of MVPs

We refer readers to our regulation at § 414.1400 and section IV.B.4. of this final rule for more detailed discussion regarding our previously finalized requirements for third party intermediaries to submit data on behalf of MIPS eligible clinicians for certain MIPS performance categories. In the CY 2022 PFS final rule (86 FR 65542 through 65544), we finalized a new requirement at § 414.1400(b)(1)(ii) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, qualified clinical data registries (QCDRs) and qualified registries (as these terms are defined at § 414.1305) must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. This regulatory provision does not specifically address by when the QCDRs and qualified registries must support the MVPs. However, since finalizing this policy in the CY 2022 PFS final rule, QCDRs and qualified registries have been expected to be ready to support each newly finalized MVP that are applicable to their MIPS eligible clinicians for the first year of the MVP's implementation.

We acknowledged that some QCDRs and qualified registries may have difficulties programming new measures and preparing their systems to support MVP reporting within the brief timeframe from when we typically issue the PFS final rule and its effective date, which only allows 2 months for implementation (typically from November of 1 year to January of the next year). We heard concerns from QCDRs and qualified registries regarding feasibility of meeting this requirement at § 414.1400(b)(1)(ii), such as the cost of implementing registry measures and working with other parties who may charge for QCDR measure use. QCDRs and qualified registries that are not ready to support applicable MVPs risk termination as they would not be in compliance with the requirement to support all applicable MVPs. Withdrawal and termination would also result in the removal of QCDR measures implemented in MIPS.

On these bases, in the CY 2026 PFS proposed rule (90 FR 32704 through 32705), we proposed to modify the language currently set forth at § 414.1400(b)(1)(ii). As discussed previously, § 414.1400(b)(1)(ii) currently provides that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. We proposed to modify § 414.1400(b)(1)(ii) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than 1 year after finalization of the MVP in accordance with the current requirement. We also proposed to sunset the current requirement as of the end of the CY 2025 performance period/2027 MIPS payment year. We proposed to retain the remaining language currently set forth at § 414.1400(b)(1)(ii) without modification.

This proposed modification will provide QCDRs and qualified registries with 1 year following the effective date of the final rule for programming and system preparation for MVP reporting success and reduce potential of withdrawal or termination.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to provide additional time for QCDRs and qualified registries to implement and fully support new MVPs. Commenters appreciated CMS' recognition of some of the technical and logistical challenges involved in adapting systems to support

new reporting requirements and stated their belief that this delay will allow for improved implementation. A commenter recommended that CMS urge QCDRs and qualified registries not to use this extended timeline to delay, but rather to complete any necessary modifications by the earliest practicable convenience. The commenter believes this would allow MIPS participants to utilize these reporting methods as soon as available, as well as make completion, testing, and usability likely to be complete before the 1-year mark.

Response: We thank commenters for their support and feedback.

Comment: Several commenters urged CMS to adopt a minimum 24-month timeframe for QCDRs, qualified registries, and certified EHRs to fully support new MVPs, citing the need for sufficient development, testing, certification, and deployment, in addition to allowing clinicians time to engage and onboard with intermediaries. A commenter believes a timeframe less than 24 months increases the likelihood of fragmented implementations, higher costs, and unintended disruptions to clinicians, all which oppose CMS' broader goals of reducing provider burden and supporting safe, effective clinical decision-making. Another commenter indicated that many intermediaries do not support all MVPs, forcing practices to engage multiple intermediaries, which increases costs, resource demands, and coordination challenges due to differing data submission processes and reporting formats.

Response: A 12-month timeframe should be sufficient time for development, testing, certification, and deployment, in addition to allowing clinicians time to engage and onboard with intermediaries. Each MVP goes through a multi-year process before inclusion within MIPS, during which time QCDRs, qualified registries, and certified EHRs can begin planning based on applicability. In addition, MVP candidates are posted for public comment a year prior to being finalized within MIPS. As specified in the CY 2022 PFS final rule (86 FR 65542 through 65544) and codified at § 414.1400(b)(1)(ii), all intermediaries are required to support the MVPs applicable to their users, which should decrease the need to engage multiple intermediaries.

Comment: A few commenters were concerned about the current requirement for third party intermediaries to support all measures within an MVP. A commenter believes it should be up to the QCDR to determine which MVPs and quality measures they plan to support. Another commenter requested clarification on whether QCDRs and qualified registries must support MVP measures that are

general in nature rather than specialty-specific. This commenter stated that requiring support for such "generic" measures would impose unnecessary burden without meaningful benefit, and recommended flexibility for QCDRs and qualified registries to determine whether broadly applicable measures add value for their clinicians. Similarly, other commenters stated concerns about supporting non-specialty-specific measures within MVPs, with a commenter recommending exemptions or opt-outs for registries unable to support certain measures. In addition, a few commenters requested that each MVP include at least four measures per collection type to reduce development costs, lower physician burden, and still maintain measure variety and relevance.

In contrast, a few commenters recommended stronger requirements, stating that a loophole currently allows intermediaries to bypass the expectation of supporting all MVP measures if they do not collect data for a given measure through the exceptions. The commenters believe this undermined the integrity of MVP reporting and created inconsistencies in clinician access to measures, and recommended CMS consider requiring documented justification for exceptions. The commenters also noted that many EHR vendors lack support for key data elements required by MIPS measures, preventing clinicians from selecting certain measures.

Response: We will take the suggestions into consideration. To clarify, we do not assign specific MVPs to third party intermediaries. The third party intermediaries should identify and support MVPs that are relevant and applicable to the clinicians and groups they support. We expect that QCDRs and qualified registries who support MVPs will support all measures and activities that are included in the MVP as required at § 414.1400(b)(1)(ii). We acknowledge that broadly applicable measures may not always be the most meaningful measures to report for a specific clinician. However, we have to account for MIPS eligible clinicians with narrowed scopes of care or case-mix, which makes it difficult for them to meet the four measure requirement for MVP reporting when there are no broadly applicable measures available. This may be due to insufficient denominator eligible cases or that the quality action being assessed is not within their scope of care; therefore, the specialized measures may not be applicable or appropriate for them to report. We include broadly applicable measures to ensure these clinicians can still meet MVP reporting requirements. In addition, there are clinical concepts that are important regardless of specialty and these measures allow for the capture of those for comparison across multiple specialties. We

require that all measures within an MVP are available for reporting to ensure clinician choice, MVPs are being implemented as consistently as possible, and measure adoption is not hindered.

We strive to maintain the integrity of MVP reporting and clinician access to measures and appreciate the feedback. While we acknowledge the concern regarding the exceptions, currently we do not require intermediaries to provide justification if an exception is applicable. We may consider stronger requirements for the justification for exceptions in future rulemaking. We also acknowledge the concern that some EHR vendors lack support for key data elements required by MIPS measures. EHR vendors that self-nominate as a QCDR or qualified registry are required to support all measures, though not all collection types, and activities available in the MVP that are applicable to its eligible clinicians.

We continue to encourage the development of quality measures across multiple collection types through our established pre-rulemaking processes, as we are limited to the current quality measure inventory. We encourage commenters to reach out to measure stewards to expand collection types for possible future implementation.

After consideration of public comments, we are finalizing our proposal to modify the requirement for QCDR and qualified registries support for MVPs as proposed.

b. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning with the CY 2021 performance period/2023 MIPS payment year. The APP was designed as a reporting and scoring pathway available only to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM as defined in § 414.1305 (MIPS APM participants) (§ 414.1367(a)). The APP provides a predictable and consistent MIPS reporting option to reduce reporting burden for, and encourage continued APM participation by, these clinicians. We also established in the APM Performance Pathway for Shared Savings Program ACOs providing that, beginning with the Shared Savings Program performance year 2021 (CY 2021 performance period/2023 MIPS payment year), ACOs were required to report quality data for purposes of the Shared Savings Program via the APP (42 CFR 425.512(a)(3); 85 FR 84722).

In that same rule, we finalized a quality measure set (85 FR 84860 and 84861) for purposes of quality performance category scoring for the APP. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we established that such measure would be removed from the quality performance category score for such MIPS eligible clinician, group, or APM Entity (85 FR 84861).

In the CY 2025 PFS final rule (89 FR 98562), we finalized a second, optional quality measure set within the APP, called the APP Plus quality measure set, to align with the Universal Foundation measure set. The measure set currently includes the current APP quality measures and 2 additional quality measures from the Adult Universal Foundation measure set. As discussed in the CY 2025 PFS final rule, we intend to incrementally add the remaining 3 Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. We also finalized a 1-year delay to the CY 2026 performance year/2027 MIPS payment year in the incorporation of the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure.

Further, for MIPS eligible clinicians, groups, and APM Entities reporting through the APP, we established in the CY 2021 PFS final rule (85 FR 84907) that we would not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP quality measure set is determined to be topped out. Because the APP quality measure set is fixed, we noted that it would not be appropriate to limit the maximum quality performance category score available to APP reporters. Should an APP quality measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

In the CY 2024 PFS final rule (88 FR 79329), we established the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP quality measure set and finalized that the Medicare CQM collection type would be available to only ACOs participating in the Shared Savings Program.

(2) Updates to Quality Measures in the APP and APP Plus Quality Measure Sets

In the CY 2021 PFS final rule, we adopted the original APP quality measure set (85 FR 84860 and 84861). Table 52 contains the original APP quality measure set. In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over four years (89 FR 62024), including by incorporating into the APP Plus quality measure set the measures from the original APP quality measure set.

To conform with changes to the MIPS quality measure inventory, as set forth in Table Group DD and Table Group C of this final rule, we proposed to incorporate the updated versions of MIPS quality measures used in the APP quality measure set. We refer to readers the proposed revisions to the following MIPS measures:

- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134)
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484). Because the APP is a reporting pathway within MIPS, all of the quality measures offered through the APP are the MIPS versions of the measures. As such, we generally take the approach of adopting changes to APP and APP Plus quality measures to conform with changes to the same measures within MIPS as a whole.

In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over 4 years (89 FR 62024). As finalized, the APP Plus quality measure set currently consists of all the measures currently within the APP quality measure set (5 Adult Universal Foundation measures and a separate quality measure) plus 1 additional measure from the Adult Universal Foundation measure set, with the intention of incrementally incorporating the remaining measures from the Adult Universal Foundation measure set by the CY 2028 performance year/2030 MIPS payment year. We finalized this incremental approach in part to allow for both the eCQM and, for Shared Savings ACOs, Medicare CQM collection types to be developed and become available.

We refer readers to Table 52 for the APP quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. The APP Plus quality measure sets for the CY 2026, 2027, and 2028 performance periods and subsequent performance periods are displayed in Tables C-BC1, C-BC2, and C-BC3 respectively.

Because the APP is a feature within MIPS and therefore the quality measures used within the APP and APP Plus quality measure sets are all MIPS measures, any updates CMS applies to MIPS measures also are incorporated into the APP and APP Plus quality measure sets, accordingly. As set forth in Table Group DD and Table Group C of this final rule, we proposed the following changes to and the removals of the following measures that are part of the APP Plus quality measure set:

- Breast Cancer Screening (Quality ID: 112)
- Colorectal Cancer Screening (Quality ID: 113)
- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134; eCQM collection type only)
- Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID:484)
- Screening for Social Drivers of Health (Quality ID: 487)

These changes have been reflected in Tables C-BC1, C-BC2, C-BC3, and C-BC4. For further discussion and rationale for the proposed modification or removal of these measures is provided at Table Group DD and Table Group C of this final rule. Again, because the APP is a reporting pathway within MIPS, all of the quality measures offered through the APP are the MIPS versions of such measures, and

we generally take the approach of adopting updates made to the MIPS measures for use in the APP quality measure sets.

TABLE C-BC1: APM PERFORMANCE PATHWAY QUALITY MEASURE SET BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/ Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE C-BC2: APP PLUS QUALITY MEASURE SET FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE C-BC3: APP PLUS QUALITY MEASURE SET FOR THE CY 2027 PERFORMANCE

PERIOD/2029 MIPS PAYMENT YEAR

QUALITY #	MEASURE TITLE	COLLECTION TYPE	SUBMITTER TYPE	MEANINGFUL MEASURES 2.0 AREA	MEASURE TYPE
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of	eCQM (all APP reporters)	MIPS Eligible Clinician	Behavioral Health	Process

QUALITY #	MEASURE TITLE	COLLECTION TYPE	SUBMITTER TYPE	MEANINGFUL MEASURES 2.0 AREA	MEASURE TYPE
	Substance Use Disorder Treatment	Medicare CQM (SSP ACOs only)	Representative of a Practice APM Entity Third Party Intermediary		

TABLE C-BC4: APP PLUS QUALITY MEASURE SET BEGINNING WITH THE CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR AND SUBSEQUENT PERFORMANCE PERIODS/MIPS PAYMENT YEARS

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity	Wellness and Prevention	Process

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
			Third Party Intermediary		
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
493*	Adult Immunization Status	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

* Indicates this measure will be incorporated into the APP Plus quality measure set in the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specification becomes available, whichever is later.

We received public comments on our proposals to conform with changes to the MIPS quality measure inventory, as set forth in Table Group DD and Table Group C of this final rule. The following is a summary of the comments we received and our responses. For responses to specific measures, we have addressed it in section X.XX of this final rule.

Comment: Many commenters expressed support for the CMS proposal, highlighting its potential to reduce burden by aligning changes to quality measures along with the broader program.

Response: We appreciate the commenters for their support. To maintain internal consistency of the measures used within the APP and APP Plus quality measure sets with MIPS overall, we are finalizing the updates to the APP and APP Plus measure sets as proposed.

c. Toward Digital Quality Measurement in CMS Quality Programs – Request for Information

We have previously issued requests for information (RFIs) to gather public input on the transition to digital quality measurement (dQM) for CMS programs.[430] This RFI provided updates on our progress and seeks input as we continue our path forward in the dQM transition.

In the CY 2026 PFS proposed rule, we solicited comments on our anticipated approach to the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting (90 FR 32710 through 32715). Currently, several CMS programs use, or are considering using, eCQMs for various clinicians, facilities, providers, and other organizations to report their respective quality performance data. These CMS programs include the Medicare Shared Savings Program (Shared Savings Program) and the Quality Payment Program, particularly the Merit-Based Incentive Payment System (MIPS) quality performance category. Specifically, we also solicited feedback on key components of the ongoing dQM transition related to FHIR-based eCQMs for the Shared Savings Program and the MIPS quality performance category. These components include: (1) FHIR-based eCQM conversion progress; (2) Data standardization for quality measurement and reporting; (3) The timeline under consideration for FHIR-based eCQM reporting; (4) Measure development and reporting tools; and (5) FHIR Reporting and Data Aggregation for ACOs (90 FR 32710 through 32715).

We received many comments on this RFI and we thank commenters for their responses. Although we will not be addressing the comments received in response to this RFI in this final rule, we value the input received and will take the comments into consideration to help us consider potential future rulemaking of policies for transition to digital quality measurement in CMS programs.

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[430] We refer readers to the following rules which contain the previous RFIs: FY 2022 IPPS/LTCH PPS final rule (86 FR 45342 through 86 FR 45349); FY 2023 IPPS/LTCH PPS final rule (87 FR 49181 through 87 FR 49188); CY 2022 Physician Fee Schedule (PFS) final rule (86 FR 65377 through 86 FR 65382); CY 2023 PFS proposed rule (87 FR 46259 through 87 FR 46262); CY 2022 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule (86 FR 63815 through 86 FR 63822); and CY 2022 End-Stage Renal Disease (ESRD) PPS final rule (86 FR 61941 through 86 FR 61948).

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, CY 2024, and CY 2025 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, 87 FR 70047 through 70055, 88 FR 79329 through 79338, and 89 FR 98373 through 98375, respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In the CY 2026 PFS proposed rule (90 FR 32715), we proposed to:

● Amend the definition of the term “high priority measure” to remove references to health equity at § 414.1305; and

● Modify the MIPS quality measure set as described in Appendix 1 of this final rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) High Priority Measure Definition

The Meaningful Measures Initiative provides for the identification of high priority areas for quality measurement and quality improvement, which identifies the core quality of care issues that advance our work to improve patient outcomes (83 FR 59719). To further identify priority areas for MIPS quality measurement, we defined the term “high priority measure” at § 414.1305, beginning with the CY 2019

performance period/2021 MIPS payment year, as an "outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure" (83 FR 59761). In the CY 2023 PFS final rule (87 FR 70047 through 70049), we finalized an amended definition of the term "high priority measure" to include quality measurement pertaining to health equity. We also codified this revised definition at § 414.1305 beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70047 through 70048). In the CY 2023 PFS final rule (87 FR 70047), we noted significant and persistent inequities in healthcare outcomes exist in the United States and that we are committed to developing innovative solutions that support access to high quality care and promote health equity, including the exploration of solutions to measure health equity within MIPS. Consequently, we stated that we believed it was imperative to include quality measures pertaining to health equity as high priority measures in order to incentivize the adoption of health equity measures by MIPS eligible clinicians. In the CY 2023 PFS final rule (87 FR 70049) we defined health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes." This definition was adopted during the Public Health Emergency (PHE) for COVID-19. At the time we believed that adding the term health equity to our definition of a "high priority measure" was the best way to address health disparities exacerbated by the pandemic. On September 12, 2023, the Department of Health and Human Services (HHS) announced the end of the Federal PHE for COVID-19 in a statement effective May 11, 2023[431]. Now that the PHE has ended, we believe that these disparities are best addressed through other mechanisms. We believe that our definition of "health equity" was confusing and that health disparities are best addressed through efforts to improve overall healthcare quality for all beneficiaries. Therefore, in the CY 2026 PFS proposed rule (90 FR 32715) we proposed to remove "health equity" from the definition of "high priority measure". Additionally, we requested public input to identify measures around well-being and nutrition as new high priority areas for quality measurement and quality improvement. The following is a summary of the comments we received and our responses.

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[431] Available at https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.

Comment: Several commenters supported the proposal to remove health equity from the definition of a high priority measure because the change would align the definition across CMS quality reporting programs. The commenters stated that the alignment would allow clinicians and health IT developers to focus on a consistent set of measure types across the care continuum, supporting streamlined reporting and reducing burden and confusion.

Response: We thank the commenters for their feedback.

Comment: Many commenters did not agree with the removal of health equity from the high priority measure definition. Commenters believe that disparities across racial, ethnic, socioeconomic, and other lines continue to exist and stated the view that removing health equity from the definition of a high priority measure undermines efforts to address those disparities and diminishes efforts to improve quality and outcomes across all patient populations.

A few commenters also stated that health equity is integral to improving healthcare quality and patient safety and experience. A few commenters stated that development of quality measures focused on health equity should be prioritized. A few commenters stated the view that reducing disparities in health outcomes cannot be achieved simply through efforts to improve health care quality for all but instead requires targeted efforts. A commenter stated that it does not regard measures assessing health, happiness, and life satisfaction as substitutes for health equity measures.

Response: We share the goal of improving healthcare quality and patient safety and experience, but we continue to believe that health disparities are best addressed through other mechanisms including improvements to healthcare quality and patient safety. We encourage the commenters to continue to identify gaps in care quality, which could be addressed through other internal clinician and health care organization quality improvement efforts separate from Federal quality reporting programs such as MIPS. We are reshaping the MIPS quality measure inventory to focus on different high-priority measures, as determined by the current administration, fewer process measures, and more outcome-based measures that align across quality reporting programs[432] (for example, XXX) and payers. Any new measures added

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[432] See, for example, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule.

to MIPS to support this effort will continue to be developed in accordance with current processes. While we agree that the previous definition may have been important for driving high quality care for all, the removal of health equity does not preclude related quality actions from continuing. Further, the removal of health equity does not lessen the focus on improving health care quality and patient safety and experience. Instead, replacing it with a wellness-based subcategory broadens the perspective to emphasize prevention, holistic care, mental and behavioral health, and lifestyle approaches that promote well-being for all individuals. This expanded framing encourages a more inclusive and proactive approach that supports better health across diverse populations. By highlighting wellness and comprehensive care, the new structure helps clinicians and organizations focus on practical strategies that strengthen overall patient outcomes and community health.

Comment: A few commenters requested CMS to clarify how reporting of equity-focused data will be advanced without health equity explicitly included in the high-priority measure definition. A commenter stated that although they supported the proposed revision of the high priority measure definition to remove health equity, they believe continued collection and analysis of equity-related data is important and will play a role in the Make America Healthy Again efforts.

Response: We note that the removal of health equity from the definition of a high priority measure does not preclude related quality action from continuing and does not lessen the focus on improving health care quality and patient safety and experience. Instead, replacing it with a wellness-based subcategory broadens the perspective to emphasize prevention, holistic care, mental and behavioral health, and lifestyle approaches that promote well-being for all individuals. This expanded framing encourages a more inclusive and proactive approach that supports better health across diverse populations. By highlighting wellness and comprehensive care, the new structure helps clinicians and organizations focus on practical strategies that strengthen overall patient outcomes and community health.

Comment: A commenter noted that if CMS removes health equity from the high priority measure definition, the agency should consider eliminating high priority measures in general because the commenter believes it adds complexity without adding value to the program.

Response: We are finalizing to remove health equity from the high priority definition. However, we do not agree that we should remove high priority measures at this time as they align with our National

Quality Strategy. They are important to ensure clinicians focus on the most impactful aspects of patient care, driving improvement in crucial areas. For example, high priority measures include outcome, patient safety, and patient experience measures, which focus on the most important results of healthcare interventions. Additionally, high priority measures are included in our data submission requirements for traditional MIPS as clinicians must submit collected data for at least 6 quality measures (including one outcome measure or high priority measure in the absence of an applicable outcome measure), or a complete specialty measure set. Further, high priority measures are included in our data submission for MVPs as an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure).

Comment: A commenter requested that CMS continue to invest in developing and refining health equity related measures, provide technical assistance and resources to support implementation of those measures, especially for small and rural practices, and align health equity measurement across programs to reduce burden and confusion. A commenter stated that in light of the proposed removal of health equity measures from the definition of a high priority quality measure, they wished to highlight the importance of considering environmental and social factors to ensuring success of surgical care.

Response: We are committed to the success of small and rural practices and efforts for alignment which reduce burden and confusion. We note that we currently offer assistance through the CMS help desk which may be reached at QPP@cms.hhs.gov. For more information about the resources available please see https://www.cms.gov/about-cms/information-systems/hpms/help-desk-information. We thank commenters for highlighting the importance of considering environmental and social factors to ensuring surgical care success. We are committed to improving healthcare quality including surgical care.

After consideration of the comments on this proposal we are finalizing our revision to the definition of "high priority measure" as proposed. Specifically, we are amending the definition of the term "high priority measure" at § 414.1305 to mean an "outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure" beginning with the CY 2026 performance period/ 2028 MIPS payment year.

(c) Selection of Quality Measures

(i) Addition of New Quality Measures

(A) Pre-Rulemaking Process

Prior to introducing a new MIPS quality measure in a proposed rule, we receive public input on measures through the pre-rulemaking process (referred to as the Pre-Rulemaking Measure Review (PRMR)) established in accordance with section 1890A of the Act. Although section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-stakeholder workgroups and have accordingly elected for such measures to be reviewed utilizing the PRMR process (87 FR 70048). Under the established PRMR process (additional information regarding the PRMR process is available at https://p4qm.org/PRMR), CMS has contracted with a Consensus-Based Entity (CBE), which is responsible for convening a multi-stakeholder panel comprised of clinicians, patients, measure experts, and health information technology specialists to provide input on measures CMS is considering for use in Medicare.

The pre-rulemaking process begins with CMS's publication of measures under consideration for use in Medicare (the MUC List). Each measure on the MUC List is reviewed by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary. The PRMR process includes opportunities for public comments through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.

The final vote of a multistakeholder committee convened by the CBE may result in the following disposition of a measure: recommended, recommended with conditions, do not recommend, or no consensus. A "no consensus" recommendation signals continued disagreement among the committee despite being presented with perspectives from public comments, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. Quality measures that are considered for potential implementation in MIPS starting with CY 2026 performance period/2028

payment year period were included on the 2024 Measures Under Consideration (MUC) List (available at https://mmshub.cms.gov/sites/default/files/2024-MUC-List.xlsx). The new MIPS quality measures as finalized are described in Table Group A of Appendix 1 of this final rule. There may be cases in which the CBE does not recommend a measure to move forward to the rulemaking process and eventual implementation due to a measure not being endorsed by the CBE or other CBE, but we go forth with proposing a measure. We note that section 1848(q)(2)(D)(iii)(v)(III) of the Act does not preclude the Secretary from proposing and implementing measures that are not endorsed by a CBE as long as the measure is evidence-based.

(ii) Removal of Quality Measures

In the CY 2025 PFS final rule, we codified previously established criteria for the removal of MIPS quality measures from the MIPS quality measure inventory at § 414.1330. In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we established the following criteria for measure removal to include: If the Secretary determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out; and, if a measure steward is no longer able to maintain the quality measure. In the CY 2019 PFS final rule (83 FR 59763), we expanded the criteria for measure removal to include MIPS quality measures that reached an extremely topped-out status (for example, a measure with an average mean performance within the 98th to 100th percentile range); the MIPS quality measure may be proposed for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped-out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Also, in the CY 2019 PFS final rule (83 FR 59764), we established other criteria for measure removal, specifically MIPS quality measures that are: duplicative; not maintained or updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice; and low-bar, standard of care process measures. As described in the CY 2019 PFS final rule (83 FR 59765), we established an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to the following:

- Whether the removal of the process measure impacts the number of measures available for a

specific specialty.

- Whether the MIPS quality measure addresses a priority area highlighted in the Measure Development Plan: https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measuredevelopment.html.
- Whether the MIPS quality measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS quality measure is designated as high priority or not.
- Whether the MIPS quality measure has reached extremely topped-out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

In the CY 2020 PFS final rule (84 FR 62958 through 62959), we expanded the criteria for measure removal to include MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods and not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. For MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods, we noted that we will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; and consideration of the MIPS quality measure in developing MVPs) prior to determining whether to remove the MIPS quality measure.

(iii) Inventory of Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2025 PFS final rule (89 FR 98599 through 98954), CY 2024 PFS final rule (88 FR 79556 through 79964), CY 2023 PFS final rule

(87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968), CY 2021 PFS final rule (85 FR 85045 through 85377), CY 2020 PFS final rule (84 FR 63205 through 63513), CY 2019 PFS final rule (83 FR 60097 through 60285), CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174), and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We are finalizing changes to the MIPS quality measure inventory, as set forth in Appendix 1 of this final rule, including the following: the addition of new measures; updates to specialty sets (that is, creation of new specialty sets; addition and/or removal of measures; and substantive changes to existing measures within specialty sets); removal of existing measures; and substantive changes to existing measures. For the CY 2026 performance period, we are finalizing an inventory of 190 MIPS quality measures.

On January 4, 2025, we announced that we will be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 10 (CY 2017 performance period/2019 MIPS payment year through CY 2026 performance period/2028 MIPS payment year) of MIPS under the Quality Payment Program.[433] The recommendations we received were based on the MIPS quality measures finalized in the CY 2025 PFS final rule and the 2024 MUC List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, and/or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are finalized in this rule. We are finalizing modifications to existing specialty sets as described in Table Group B of Appendix 1 of this final rule. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty. We develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice.

In CY 2026 PFS proposed rule (90 FR 32874 through 33255) we proposed to modify the quality performance category measure inventory, a set of 190 MIPS quality measures, for the CY 2026 performance period/2028 MIPS payment year, which included the following:

- Implementation of 5 new MIPS quality measures including 3 high priority measures, one of which is a patient reported outcome measure;

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[433] Message to the Quality Payment Program listserv on January 4, 2025, entitled "The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2026 Performance Year of the Merit-based Incentive Payment System (MIPS)."

- Removal of 10 MIPS quality measures: 1 quality measure at the measure steward's request due to not being aligned with current clinical guidelines, 4 quality measures that are extremely topped out, 1 quality measure that has reached the end of the topped-out measure lifecycle, 1 measure where the measure steward is no longer able to maintain the quality measure, 3 process measures, and;
- Substantive changes to 32 MIPS quality measures.

In the CY 2026 PFS (90 FR 32874 through 33255) we proposed new MIPS quality measures for inclusion in MIPS for the CY 2026 performance period/2028 payment year and future years can be found in Table Group A of Appendix 1 of this final rule. For the CY 2026 performance period/2028 MIPS payment year, we proposed 5 new MIPS quality measures, which include 3 high priority measures, one of which is also a patient-reported outcome measure.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets as described in Tables Group A and Group B of Appendix 1 of this final rule, we refer readers to Table Group C of Appendix 1 of this PFS final rule for a list of MIPS quality measures finalized for removal and applicable rationale for each measure. In the 2025 PFS final rule (89 FR 98388), we codified previously finalized removal criteria for MIPS quality measures at 42 CFR 414.1330(c). Of the 10 MIPS quality measures finalized for removal, 1 MIPS quality measure is being removed at the measure steward's request and is not aligned with current clinical guidelines), 4 MIPS quality measures are extremely topped out, 1 MIPS quality measure has reached the end of the topped-out measure lifecycle, 1 MIPS quality measure is no longer able to be maintained by the measure steward, and 3 are process measures. For a detailed discussion of our rationale for the removal of these measures please see Table Group C of Appendix 1 of this final rule. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see*, for example, 83 FR 59763 through 59765). The finalized policy to remove the MIPS quality measures described in Table Group C of Appendix 1 of this final rule would lead to a more parsimonious inventory of meaningful, robust measures in the program.

Additionally, we are finalizing substantive changes to 30 MIPS quality measures, which can be found in Table Group D of the Appendix 1 in this final rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137,

and 86 FR 65441 through 65442). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. The finalized inventory of 190 MIPS quality measures includes 187 MIPS quality measures available for utilization in traditional MIPS and MVPs, and 3 MIPS quality measures available only for utilization in MVPs (as finalized in the CY 2024 PFS final rule (88 FR 79897 through 77902)).

We refer readers to Table Groups A through DD of Appendix 1 of this final rule for a summary of the new measures finalized, the measures finalized for removal, and the substantive changes finalized. We received public comments on these proposals. The comments and responses may be found in Appendix 1 of this final rule.

(2) Cost Performance Category

(a) Background

Section 1848(q)(2)(A)(ii) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the cost performance category.

Section 1848(q)(2)(B)(ii) of the Act provides that, for the cost performance category, the measurement of resource use (that is, cost) for such period must be in accordance with section 1848(p)(3) of the Act, using the methodology under section 1848(r) as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Medicare Part D. Section 1848(p)(3) of the Act provides that costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary that eliminate the effect of geographic adjustments in payment rates, and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals) and other factors determined appropriate by the Secretary. Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act.

In the CY 2026 PFS proposed rule (90 FR 32718), we proposed the following updates to the cost performance category beginning with the CY 2026 performance period/2028 MIPS payment year:

- Modify the MIPS cost measure inventory as described in Appendix 4 of this rule;
- Update the operational list of care episode and patient condition groups and codes to reflect changes to service and diagnosis codes that define care episodes and patient condition groups, as identified through the annual maintenance of episode-based measures; and
- Adopt a 2-year informational-only feedback period for new cost measures, where a measure will not impact MIPS cost performance category scores, final scores, or payment adjustments until the third year it is implemented.

For a description of the statutory authority for and existing policies pertaining to the cost performance category, we refer readers to §§ 414.1350 and 414.1380(b)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), and CY 2025 PFS final rule (89 FR 98390 through 98408).

More details on the finalized proposals in this section, which we solicited comments on, are provided in section IV.A.4.d.(2)(b) through section IV.A.4.d.(2).(d). of this final rule. We also refer readers to section V.B.5.c. of this final rule for discussion on the burden estimates for these proposals.

(b) Selection of Cost Measures

In accordance with our statutory authority as described in section IV.A.4.d.(2)(a) of this final rule and at § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. We refer readers to the CY 2026 PFS proposed rule (90 FR 32718) for additional context on the considerations for cost measure selection.

(c) Inventory of Cost Measures

As discussed previously, we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. There are currently 35 cost measures in the cost performance category for the CY 2025 performance period/2027 MIPS payment year, comprising 33 episode-based measures covering a range of conditions and procedures and 2 population-based measures. Previously finalized MIPS cost measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), and CY 2025 PFS final rule (89 FR 98390 through 98408). We refer readers to the CY 2026 PFS proposed rule (90 FR 32718 through 32719) for more context on how we establish the inventory of cost measures, including the pre-rulemaking requirements.

We neither proposed any new MIPS cost measures nor proposed to remove any MIPS cost measures for the CY 2026 performance period/2028 MIPS payment year. In the CY 2026 PFS proposed rule (90 FR 32719) we proposed substantive changes to one cost measure, which can be found in Table Group A of Appendix 4 of this final rule, beginning with the CY 2026 performance period/2028 MIPS payment year.

We solicited and received public comments on the proposal to modify one cost measure. We refer readers to Table Group A of Appendix 4 of this final rule for a summary of the public comments received regarding the proposed modifications to one cost measure beginning in the CY 2026 performance period and the discussion regarding final decisions.

After consideration of public comments, and for the reasons stated in the aforementioned Table Group A of Appendix 4 of this final rule and the CY 2026 PFS proposed rule (90 FR 33258 through 33261), we are finalizing the modifications to the one cost measure as proposed.

(d) Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

In accordance with section 1848(r)(2)(H) of the Act, in the CY 2026 PFS proposed rule (90 FR 32719) we proposed to revise the operational list beginning with the CY 2026 performance period/2028 MIPS payment year to reflect changes to codes used to identify existing care episode and patient condition groups, based on new information gathered during annual maintenance of episode-based measures and the Medicare Spending Per Beneficiary (MSPB) Clinician measure. We conduct annual maintenance for measures implemented in MIPS to ensure that the codes used for the measure specifications remain up to date. For example, we may update the service or diagnosis codes associated with a cost measure's specifications to retain the intent of the measure when these codes are changed in, added to, or deleted from the applicable code sets. During our annual maintenance review process for MIPS cost measures, we worked with the measure developer to identify several non-substantive changes to service and diagnosis codes that should be reflected in the operational list care episode and patient condition groups so that, to the extent feasible, there is alignment between the operational list and measure specifications. More information on the annual maintenance process is available at the CMS Measures Management System (MMS) page at *https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/annual-update*.

For context on the statutory requirements for care episode and patient condition groups and changes to the operational list, we refer readers to the CY 2026 PFS proposed rule (90 FR 32719 through 32720).

Our revisions to the operational list are available for review on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about*.

We solicited and received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the proposed updates to the operational list of care episode and patient condition groups and codes.

Response: We thank the commenters for their support.

Comment: A commenter stated that updates to the operational list of care episode and patient condition groups and codes, such as diagnosis code updates, could change TPCC measure attribution. This commenter suggested that CMS involve specialty societies and technical expert panels when making any coding updates to avoid unintended consequences for cost measures, including changes to triggering logic or attribution methodologies.

Response: The operational list of care episode and patient condition groups and codes only contains care episode and patient condition groups. The TPCC measure is not based on care episode or patient condition groups and is therefore not included in this document. The operational list is annually updated through rulemaking, as statutorily required under section 1848(r)(2)(H). In the CY 2026 PFS proposed rule (90 FR 32719), we proposed updates to the operational list so that the list reflects the most recent non-substantive updates we made to the Medicare Spending Per Beneficiary (MSPB) Clinician measure and episode-based measures through annual maintenance. We refer readers to the CY 2026 PFS proposed rule (90 FR 32718 through 32719) for a description of the cost measure maintenance process. We refer readers to Table Group A of Appendix 4 of this final rule for more information on modifications to the TPCC measure.

After consideration of public comments, we are finalizing as proposed to revise the operational list beginning with the CY 2026 performance period/2028 MIPS payment year to reflect changes to codes used to identify existing care episode and patient condition groups.

(e) Adopt a 2-Year Informational-Only Feedback Period for New MIPS Cost Measures

(i) Background on Informational-Only Feedback Period

Section 1848(q)(2)(B) of the Act provides that MIPS measures and activities must be specified for a performance period for each of the four performance categories, including the cost performance category as set forth in section 1848(q)(2)(B)(ii) of the Act. Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards with respect to applicable measures and activities specified in accordance with section 1848(q)(2)(B) with respect to each performance category. Section 1848(q)(5)(A) of the Act further directs the Secretary to provide for a composite assessment (that is, a MIPS final score) for each MIPS eligible clinician for the applicable performance period for such MIPS payment year using such methodology. At § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category.

Currently, we assess a MIPS eligible clinician's performance on any measure we have specified for the MIPS cost performance category for a performance period that is attributed to a MIPS eligible clinician in accordance with § 414.1350(b)(8), calculating a score on the clinician's performance with respect to the cost measure in accordance with § 414.1380(b)(2). As we discussed in detail in the CY 2025 PFS final rule when we modified our scoring methodology (89 FR 98438 through 98446), we score cost measures by comparing a MIPS eligible clinician's attributed costs to benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the same cost measure, plus or minus standard deviations (§ 414.1380(b)(2)(i)(B)). We then calculate the cost performance category score as set forth in § 414.1380(b)(2)(iii), which we incorporate into our calculation of the MIPS final score in accordance with §§ 414.1380(c) and 414.1350(d). We then compare the MIPS final score with the performance threshold established for that MIPS payment year to calculate the MIPS payment adjustment in accordance with section 1848(q)(6) of the Act and § 414.1405. Section 1848(q)(12) of the Act further provides that we must make available timely confidential feedback to MIPS eligible clinicians regarding their performance in the cost performance category.

Many interested parties have requested more timely and transparent feedback on cost measures, specifically mentioning an informational-only feedback period for MIPS cost measures. We refer readers

to the CY 2026 PFS proposed rule (90 FR 32719 through 32720) for more discussion on the types of information MIPS eligible clinicians receive about cost measures, the feedback we received, and relevant considerations. We believe that an informational-only feedback period would provide MIPS eligible clinicians with information and time to develop performance improvement strategies before their performance on new cost measures affects payment or is incorporated into MIPS final scores.

(ii) Adopt an Informational-Only Feedback Period of 2 Years for New Cost Measures

Section 1848(q)(1)(A) of the Act requires that the Secretary develop a methodology for assessing the total performance of each MIPS eligible clinician, provide a MIPS final score for each MIPS eligible clinician using such methodology, and to determine and apply a MIPS payment adjustment factor for each MIPS eligible clinician using the MIPS final score. As discussed previously, section 1848(q)(5) of the Act more specifically requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician on measures and activities specified under section 1848(q)(2)(B) of the Act and to provide for a MIPS final score. As part of this methodology, we are proposing an informational-only feedback period of 2 years for new cost measures finalized for use in MIPS beginning with the CY 2026 performance period/2028 MIPS payment year.

Specifically, in the CY 2026 PFS proposed rule (90 FR 32719 through 32722) we proposed that, beginning with the CY 2026 performance period/2028 MIPS payment year, we would score all new cost measures for the first 2 years after the measure is initially finalized for informational-only purposes; we would not incorporate any informational-only scores on cost measures into MIPS eligible clinicians' cost performance category score or MIPS final score. If a MIPS eligible clinician is attributed a cost measure during its informational-only feedback period, then we would calculate a measure score in accordance with our scoring policies at § 414.1380(b)(2) and confidentially provide the score, as well as MIPS performance feedback (*see* 82 FR 53799 through 53801), to the clinician on an annual basis. As we would not include the informational-only score in our calculation of cost performance category scores or MIPS final scores, MIPS eligible clinicians' performance on the new cost measures would not affect our calculation of their MIPS payment adjustments.

We further proposed that we would begin incorporating these cost measures' scores into MIPS eligible clinicians' cost performance category and MIPS final scores beginning with the cost measure's

third year in MIPS, after this 2-year informational-only feedback period. Once we begin incorporating these measures' scores into MIPS eligible clinicians' cost performance category and MIPS final scores, then MIPS eligible clinicians' performance on these measures would also affect their MIPS payment adjustments.

While we did not propose to adopt any new cost measures in this final rule, we proposed that this policy would begin with the CY 2026 performance period/2028 MIPS payment year. We proposed that beginning with the CY 2026 performance period/2028 MIPS payment year, this policy would be in place prior to any new cost measures being added to the MIPS cost performance category through future rulemaking.

We proposed that this informational-only feedback period policy will not be applied to any existing cost measures already finalized for MIPS prior to the CY 2026 performance period/2028 MIPS payment year. We further proposed that modifications to existing cost measures will not alter whether a measure is considered a new or existing measure. We proposed this policy for measures that have not previously been implemented in MIPS so that MIPS eligible clinicians receive initial performance feedback on new cost measures without affecting their MIPS payment adjustments. The measures within the current cost measure inventory have already been implemented through the rulemaking process and are finalized for use in MIPS scoring for the CY 2025 performance period/2027 MIPS payment year. As a result, MIPS eligible clinicians have already made decisions about their MIPS participation for the CY 2025 performance period/2027 MIPS payment year based on the inclusion of existing cost measures in MIPS scoring and payment adjustments. Further, many of the existing cost measures have been in use in MIPS for several years, so MIPS eligible clinicians have become more familiar with the measure specifications and opportunities for improvement. We anticipated that this proposed informational-only feedback period will drive performance improvement for MIPS eligible clinicians, while continuing to support the statutory requirement for clinicians to be scored on cost as part of their composite performance score, as specified under section 1848(q)(5)(A) of the Act.

The timeline for new cost measures adopted after the effective date of this proposal would be as follows:

- First CY Performance Period/MIPS Payment Year: Informational-only feedback period.

- Second CY Performance Period/MIPS Payment Year: Informational-only feedback period.
- Third CY Performance Period/MIPS Payment Year: Cost measure scores will be incorporated into MIPS eligible clinicians' cost performance category and MIPS final scores, affecting their MIPS payment adjustments for the performance period's corresponding payment year.

We also proposed that cost measures within an informational-only feedback period can be included in an MVP if they are clinically relevant. MVPs aim to improve value through assessing linked performance categories, including cost and quality (86 FR 65391). As such, we will include cost measures eligible for scoring as well as measures in the informational-only feedback period in MVPs, when appropriate, consistent at § 414.1365(c)(2). CMS may create an MVP that only includes cost measures in an informational-only feedback period in instances where these are the only relevant cost measures for an MVP. Any cost measures would continue to be determined for use in an MVP in accordance with the MVP development criteria and the MVP cost reporting requirements as set forth in the CY 2022 PFS final rule (86 FR 65405 through 65409; 86 FR 65412, respectively).

We proposed that an MVP, including any cost measures within their informational-only feedback period, would continue to be scored according to all scoring policies outlined in § 414.1365(d), including § 414.1365(d)(3)(ii). Section 414.1365(d)(3)(ii) provides that we calculate the cost performance category score for the cost measures included in the MVP that an MVP participant selects and reports using the methodology at § 414.1380(b)(2), the same as for any cost measures. As we proposed to codify this informational-only feedback period policy at § 414.1380(b)(2) as discussed below, cost measures included in an MVP (that an MVP participant selects and reports) that are in their informational-only feedback period would be treated in the same manner as if the MVP participant was attributed the cost measure under traditional MIPS.

In other words, we proposed that, if a new cost measure in its informational-only feedback period is included in an MVP, then we would calculate a measure score in accordance with our proposed scoring policy at § 414.1380(b)(2) and confidentially provide the score, as well as MIPS performance feedback, to the MVP participants that select and report that MVP on an annual basis. We will not incorporate any informational-only scores on cost measures into the MVP participant's cost performance category score or MIPS final score.

The proposal will provide MIPS eligible clinicians the ability to receive informational-only feedback on their cost measure performance and their performance within an MVP, without delaying the creation of clinically meaningful MVPs in MIPS. We will provide this informational-only feedback in accordance with MIPS feedback policies, as outlined in section 1848(q)(12) of the Act. We have also heard feedback from interested parties requesting that we implement MVPs through a gradual process, where there is transparency and time for MIPS eligible clinicians to adapt to changes (86 FR 65394 through 65395). We believe that including cost measures in MVPs that are in the informational-only feedback period aligns with these requests, providing transparency and time to adapt to new cost measures that a MIPS eligible clinician may be attributed within an MVP. In addition, we seek to align scoring of MVPs with scoring of traditional MIPS whenever possible, in accordance with the MVP scoring policy outlined in the CY 2022 PFS final rule (86 FR 65419 through 65421).

We also proposed that we will not publicly report MIPS eligible clinicians' performance on cost measures within their informational-only feedback period. Public reporting of information regarding performance of eligible clinicians and groups, as required by section 1848(q)(9) of the Act, allows patients to use data to inform their care decisions. The goal of an informational-only feedback period is to provide MIPS eligible clinicians time and information to become familiar with new cost measures prior to affecting MIPS eligible clinicians. We believe that public reporting while a measure is within this feedback period would be inconsistent with the goals of this policy.

In addition, the 2-year informational-only feedback period aligns with the current structure of public reporting, where for the first 2 years that a measure is in use in MIPS, it cannot be publicly reported, as outlined at § 414.1395(c). The cost measures will be available for consideration for public reporting starting in the third year that they are in use (that is, the first year that new cost measures are included in MIPS eligible clinicians' cost performance category and MIPS final scores).

Additionally, we proposed to codify this informational-only feedback period by amending § 414.1380(b)(2). Specifically, we proposed to add this policy under several new paragraphs at § 414.1380(b)(2)(vi). First, we proposed that § 414.1380(b)(2)(vi) will provide that, beginning with the 2028 MIPS payment year, CMS will calculate a score for each new cost measure in accordance with the scoring policy set forth in this paragraph (b)(2) for informational-only purposes during the measure's

informational-only feedback period.

Second, we proposed to define the terms "new cost measure" and "informational-only feedback period" for the purposes of this paragraph (b)(2)(vi) at § 414.1380(b)(2)(vi)(A). We proposed to define "new cost measures" at § 414.1380(b)(2)(vi)(A)(*i*) as meaning a measure that CMS has newly specified for the MIPS cost performance category for a performance period at § 414.1350 beginning with the 2028 MIPS payment year. We will further provide at § 414.1380(b)(2)(vi)(A)(*i*) that this term excludes any cost measures that CMS has specified for the MIPS cost performance category prior to the 2028 MIPS payment year or CMS modifies at any time. We proposed to define "informational-only feedback period" at § 414.1380(b)(2)(vi)(A)(*ii*) as meaning a 2-year period beginning with the first day of the first performance period and ending with the final day of the second performance period for the 2 applicable MIPS payment years for which CMS initially has specified the new cost measure.

Third, we proposed to add paragraphs (B), (C), and (D) to § 414.1380(b)(2)(vi) to codify our proposed scoring of a new cost measure during and after its informational-only feedback period. We will provide at § 414.1380(b)(2)(vi)(B) that, during a new cost measure's informational-only feedback period, CMS will not include any scores for the new cost measure calculated for informational-only purposes under this paragraph (b)(2)(vi) in CMS's calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) or a MIPS eligible clinician's MIPS final score under paragraph (c) of § 414.1380. At § 414.1380(b)(2)(vi)(C), we will provide that, during a new cost measure's informational-only feedback period, CMS will confidentially provide each MIPS eligible clinician with their measure score under this paragraph (b)(2)(vi) for informational-only purposes. Also, we would provide at § 414.1380(b)(2)(vi)(C) that CMS will provide performance feedback to the MIPS eligible clinician in accordance with section 1848(q)(12) of the Act. We would provide at § 414.1380(b)(2)(vi)(D) that, upon completion of a new cost measure's informational-only feedback period, CMS will include its calculation of any scores for the cost measure in CMS' calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) and a MIPS eligible clinician's MIPS final score under paragraph (c) of § 414.1380.

Finally, we proposed to modify the paragraph at § 414.1380(b)(2)(iii) to exclude cost measure scores calculated for informational-only purposes as provided in paragraph (b)(2)(vi).

We did not propose any modification to the remaining text as currently codified at § 414.1380(b)(2)(iii).

We solicited and received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to implement an informational-only feedback period for new cost measures. Commenters stated that the informational-only feedback period would have various positive impacts, such as maintaining stability in MIPS, providing the public with more time to understand cost measures in practice, increasing transparency for cost measures, optimizing clinician performance, and allowing time for clinician education on cost measures.

Response: We appreciate the commenters' support of our proposal to implement an informational-only feedback period for new cost measures. The proposed informational-only feedback period will improve cost performance category transparency and promote clinician understanding of cost measures and awareness of performance improvement opportunities.

Comment: A commenter noted support for the proposal to delay public reporting of new cost measures during the 2-year informational-only feedback period, citing the potential for early performance data to be misleading.

Response: We appreciate the commenter's support of our proposal and our intention to align the informational-only feedback period with the public reporting timeline for cost measures.

Comment: Some commenters requested that CMS expand the informational-only feedback period policy. Specifically, some commenters requested that the policy be applied retroactively to MIPS cost measures in use for previous performance periods. Some commenters noted that this retroactive application would provide clinicians with more information before cost measure scores are tied to performance to ensure equitable treatment of clinicians attributed previously implemented cost measures. A commenter requested that CMS allow for an extended informational-only feedback period of up to 3 years for complex cost measures or changes to data systems. Another commenter requested that CMS apply the informational-only feedback period policy to newly eligible MIPS clinicians or to clinicians who have not yet been scored on a particular measure.

Response: MIPS eligible clinicians receive notice in advance of the cost measures on which they

may be scored through several avenues. As we detailed in the CY 2026 PFS proposed rule (90 FR 32720), clinicians receive notice through (1) the cost measure development process, which requires input from clinicians, specialty societies, and other interested parties as outlined in section 1848(r)(2) of the Act and the CY 2019 PFS final rule (83 FR 59770); (2) the Pre-Rulemaking Measure Review (PRMR) process, where measures are assessed for their potential use in MIPS; (3) and the notice-and-comment rulemaking process, where we propose and finalize any cost measures for use in a future MIPS performance period. During this time, clinicians have access to measure specifications and testing information for review. Furthermore, the MIPS cost measures have already been implemented through the rulemaking process and are finalized for use in MIPS scoring for the CY 2025 performance period/2027 MIPS payment year. As a result, MIPS eligible clinicians have already made decisions about their MIPS participation for the CY 2025 performance period/2027 MIPS payment year based on the inclusion of existing cost measures in MIPS scoring and payment adjustments. In addition, many of the existing cost measures have been in use in MIPS for several years, so MIPS eligible clinicians have become more familiar with the measure specifications and opportunities for improvement. Since the MIPS cost performance category is calculated using administrative claims data and clinicians do not report data for the cost performance category, we do not believe that data system updates warrant changes to the informational-only feedback policy. While we appreciate that newly eligible clinicians may need resources and assistance when first participating in the MIPS program, expanding the informational-only feedback period to apply for any newly eligible clinicians or clinicians not previously scored on a cost measure would create additional burden to track and score appropriately, and may lead to confusion for clinicians when anticipating which cost measures will impact their MIPS score.

Comment: Some commenters requested that CMS apply the informational-only feedback period to cost measures that have undergone substantive changes. A commenter stated that substantially revised cost measures introduce uncertainty for MIPS clinicians. Another commenter stated that applying this policy to cost measures with substantive changes would give clinicians more time to understand the impact of the measure revisions.

Response: The policy currently intends to provide time for clinicians to become familiar with new MIPS cost measures. We will propose and finalize any substantive changes ahead of the performance

period so that clinicians are able to understand and provide feedback on the changes to the measure specifications prior to MIPS program implementation. We will consider this feedback for potential future rulemaking.

Comment: A commenter requested that CMS add additional flexibilities to the policy to account for the effects of extreme and uncontrollable circumstances and public health emergencies (PHEs).

Response: During the prior COVID-19 PHE, clinicians and groups continued to receive feedback on cost measures. In the event of a future PHE, we would use a similar approach to cost performance category feedback, if feasible. Should the PHE extend beyond the informational-only feedback period, our existing policies, codified at § 414.1380(c)(2), offer flexibilities to any impacted MIPS participant, such as reweighting the cost performance category. We can consider additional flexibilities for this policy in future rulemaking if a need is identified.

Comment: Several commenters stated the importance of more frequent (for example, quarterly), actionable performance feedback and raised concerns that this feedback was not yet available for cost measures.

Response: As described in the CY 2025 final rule (89 FR 98398), we currently provide annual MIPS Performance Feedback that includes information on MIPS eligible clinicians' performance for the previous performance period. This feedback typically becomes available during the summer in between the performance period and the MIPS payment year. We provide these reports on an annual basis, as we calculate cost measures following the end of the performance period. We calculate and score the cost measures following the end of the performance period because we need to review all claims that fall within the scope of a cost measure for a given performance period. However, we are continuing to work towards providing meaningful and timely information on cost measures generally and we recognize the importance of providing this information for measures implemented in MIPS.

Comment: A commenter stated that CMS should clarify how scoring will work for MVPs that include cost measures still in the informational-only feedback period and should ensure that MVP participation remains fair and transparent in light of the informational-only feedback period proposal.

Response: As discussed in the CY 2026 PFS proposed rule (90 FR 32721), an MVP, including any cost measures within their informational-only feedback period, would continue to be scored

according to all scoring policies outlined in § 414.1365(d), including § 414.1365(d)(3)(ii). However, we would not include the informational-only score in our calculation of cost performance category scores or MIPS final scores, therefore MIPS eligible clinicians' performance on the new cost measures would not affect our calculation of their MIPS payment adjustments. Although we would not include the informational-only score in cost performance category or MIPS final score calculation, cost measures included in an MVP (that an MVP participant selects and reports) that are in their informational-only feedback period would be treated in the same manner as if the MVP participant was attributed the cost measure under traditional MIPS.

After consideration of public comments, we are finalizing the informational-only feedback period policy as proposed.

(3) Improvement Activities Performance Category

(a) Background

Section 1848(q)(2)(A)(iii) of the Act includes clinical practice improvement activities as a performance category under MIPS. We refer to this performance category as the improvement activities performance category. As required by section 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the improvement activities performance category.

Section 1848(q)(2)(C)(v)(III) defines the term "clinical practice improvement activities" as an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act provides that, for the improvement activities category, the Secretary shall specify subcategories of clinical practice improvement activities, including at least six subcategories as specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act. These statutorily enumerated subcategories are: (1) expanded practice access (such as same day appointments for urgent needs and afterhours access to clinician advice); (2) population management (such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry); (3) care coordination (such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth); (4) beneficiary engagement (such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision- making mechanisms); (5) patient safety and practice assessment (such as through use of clinical or surgical checklists and practice assessments related to maintaining certification); and (6) participation in an alternative payment model, as defined in section 1833(z)(3)(C) of the Act (section 1848(q)(2)(B)(iii)(I) through (VI) of the Act).

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician

Fee Schedule (PFS) final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), the CY 2023 PFS final rule (87 FR 70057 through 70061), and the CY 2024 PFS final rule (88 FR 79350 and 88 FR 79351). We also refer readers to § 414.1305 for the relevant definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

In the CY 2026 PFS proposed rule (90 FR 32722 through 32725), we proposed various updates to the Improvement Activities Inventory beginning with the CY 2026 performance period/2028 MIPS payment year, as described further later in this section. First, we proposed to remove the Achieving Health Equity subcategory. Second, we proposed adding a new subcategory to the improvement activities performance category: Advancing Health and Wellness. Third, we proposed adding three new improvement activities into two of our existing subcategories: (1) Population Management and (2) Patient Safety and Practice Assessment. Fourth, we proposed modifying seven existing improvement activities currently specified for the performance category. Fifth, we proposed removing eight improvement activities currently specified for the performance category.

We refer readers to section V.B.5.e of this final rule for discussion of the burden estimates for these proposals.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the first year of MIPS, we implemented the initial Improvement Activities Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We made several steps to ensure the Inventory was inclusive of activities aligned with statutory and program requirements. As part of this process, we conducted numerous interviews with high performing organizations of all sizes and conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities

performance category, including patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, and Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Organizations. In addition, we reviewed the comments we received in response to the MIPS and APMs Request for Information (RFI) related to the improvement activities performance category, as described in the CY 2016 PFS final rule with comment period (80 FR 71259 and 71260). For the MIPS and APMs RFI, we sought input on what activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

Beginning with the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659), we introduced an informal process for interested parties to submit new improvement activities or modifications for our consideration and potential inclusion in the comprehensive Improvement Activities Inventory. In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), beginning with the CY 2019 performance period/2021 MIPS payment year, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the Improvement Activities Inventory. This process requires interested parties to submit a nomination form similar to the one we used for the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). To submit a request for a new activity or a modification to an existing activity, the interested party must submit a nomination form (OMB control # 0938–1314) available at www.qpp.cms.gov during the Annual Call for Activities.

(ii) Update the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. For our previously finalized Improvement Activities Inventories, we refer readers to Table H in the CY 2017 Quality Payment Program final rule (81 FR 77817) Appendix, Tables F and G in the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) Appendix, Tables A and B in the CY 2019 PFS final rule (83 FR 60286 through 60303) Appendix 2, Tables A, B, and C in the CY 2020 PFS final rule (84 FR 63514 through 63538) Appendix 2, Tables A, B, and C in the CY 2021 PFS final rule (85 FR 85370 through 85377) Appendix 2, Tables A, B, and C in the CY 2022 PFS final rule (86 FR 65969 through 65997)

Appendix 2, and Tables A, B, and C in the CY 2023 PFS final rule (70633 through 70650) Appendix 2. We also refer readers to the Quality Payment Program website and the Explore Measures and Activities tool at https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2025 for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305, consistent with the statutory definition at section 1848(q)(2)(C)(v)(III) of the Act, to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

In the CY 2026 PFS proposed rule (90 FR 32722 through 32725), we proposed various updates to the improvement activities performance category, beginning with the CY 2026 performance period/2028 MIPS payment year. First, we proposed removing the Achieving Health Equity subcategory. Second, we proposed adding a new subcategory to the improvement activities performance category: Advancing Health and Wellness. Third, we proposed adding three new improvement activities into two of our existing subcategories: (1) Population Management and (2) Patient Safety and Practice Assessment. Fourth, we proposed modifying seven existing improvement activities currently specified for the performance category. Fifth, we proposed removing eight improvement activities currently specified for the performance category. Generally, the three proposed new activities will fill gaps in the Improvement Activities Inventory and the seven proposed modified activities represent updates to the clinical goals of each modified activity. Our proposal to remove eight improvement activities reflects changes in our priorities and an intent to maintain an inventory of activities that are focused on driving improved patient outcomes directly. While we acknowledge the importance of clinical work and research that address the needs of specific populations, we proposed to exclude activities that do not have a direct and measurable impact on improving patient health outcomes. If MIPS-eligible clinicians or groups identify a need for clinical quality improvement specific to a unique population under their care, they can select from existing activities in the inventory that are designed to support such targeted efforts. Our proposal focuses on removing activities that do not lead to demonstrable improvements in patient outcomes, rather than those that address specific population needs through evidence-based clinical intervention. For example,

IA_PSPA_19 (Implementation of formal quality improvement methods, practice changes or other practice improvement processes) allows for significant flexibility in the focus area of the quality improvement completed and MIPS-eligible clinicians or groups may be able to use this activity to improve clinical quality specific to a unique population under their care.

(iii) Update to Subcategories Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

As discussed previously, section 1848(q)(2)(B)(iii) of the Act provides that the Secretary specifies clinical practice improvement activities under subcategories, which must include at least six enumerated subcategories. Under section 1848(q)(2)(B)(iii) of the Act, we established the current subcategories for the improvement activities performance category at § 414.1355(c).

(1) Proposal to Remove Achieving Health Equity Subcategory Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule (90 FR 32724), we proposed to remove the "Achieving Health Equity" (AHE) subcategory beginning with the CY 2026 performance period/2028 MIPS payment year. We will also remove this subcategory from regulation at § 414.1355(c)(7), replacing it with a new subcategory as described in later in this section.

This proposal to remove the AHE subcategory would not de-emphasize our focus on improving access, enhancing care coordination, and strengthening patient engagement. The removal of this subcategory would also be aligned with other CMS programs, Hospital Quality Reporting Programs, and other MIPS performance categories, such as the Quality performance category.). Additionally, maintaining a separate subcategory can lead to overlap with other domains such as care coordination, population management, and behavioral health integration, thus increasing burden. Integrating the principle of whole-person care and applying it within the broader framework of Advancing Health and Wellness allows CMS to promote a more holistic, prevention-focused approach that supports access across all activities.

As further discussed, we also proposed to recategorize five existing improvement activities from the Achieving Health Equity (AHE) subcategory to other established subcategories to better align with the substantive focus of these activities' descriptions. This proposed recategorization also reflects a strategic shift to emphasize emerging priorities such as wellness and prevention.

We solicited public comments on our proposal to remove the Advancing Health Equity subcategory from the improvement activities performance category and from § 414.1355(c)(7) beginning with the CY 2026 performance year/2028 MIPS payment year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters opposed the removal of the Achieving Health Equity subcategory, expressing concern that its elimination would diminish efforts to address disparities in healthcare access, quality, affordability, and outcomes. Some commenters believe the replacement of the Achieving Health Equity subcategory with a wellness-based subcategory is too limited in scope to meaningfully address health disparities, whereas the Achieving Health Equity directly targets systemic inequities and social determinants of health through focused, equity-driven improvement activities. A few commenters made suggestions to keep improvement activities that focus on upstream drivers of health. A commenter recommended placing these new activities under the Patient Safety and Practice Assessment (PSPA) and Expanded Practice Assess (EPA) subcategories.

Response: The removal of the Achieving Health Equity subcategory does not lessen the focus on improving access to care, enhancing patient well-being, or supporting preventative measures that influence health outcomes. Instead, replacing it with a wellness-based subcategory broadens the perspective to emphasize prevention, holistic care, mental and behavioral health, and lifestyle approaches that promote well-being for all individuals. This expanded framing encourages a more proactive approach that supports better health across all populations. By highlighting wellness and comprehensive care, the new structure helps clinicians and organizations focus on practical strategies that strengthen overall patient outcomes and community health.

Comment: A commenter who did not agree with the proposal to remove the Achieving Health Equity subcategory stated how specific improvement activities, such as IA_AHE_7 and IA_AHE_10, could be recategorized, and that individual improvement activities should be evaluated on merit. Another commenter also stated that we should work with interested parties to retain certain improvement activities.

Response: Following a comprehensive assessment of the Improvement Activities Inventory, we

determined that reassigning five improvement activities from the Achieving Health Equity subcategory would align the Inventory with CMS' evolving priorities—specifically, preventive care, nutrition, and patient well-being (90 FR 32724). This determination was also supported by interested party comments received from the CY 2026 PFS proposed rule. IA_AHE_7 and IA_AHE_10 are being reassigned to the Beneficiary Engagement and Patient Safety and Practice Assessment subcategories, respectively, to ensure more accurate alignment between each activity's purpose and its designated subcategory. We will continue to work with interested parties across HHS and will assess new improvement activities during the Call for Improvement Activities process to ensure improvement activities continue to meet our priorities.

Comment: A few commenters supported the removal of the Achieving Health Equity subcategory. Other commenters supported the recategorization of improvement activities from the Achieving Health Equity subcategory.

Response: We appreciate commenters' support for our proposal.

After consideration of public comments, we are finalizing removing the Achieving Health Equity subcategory as proposed.

(2) Add New Advancing Health and Wellness Subcategory Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule (90 FR 32724), we proposed to add a new subcategory, titled "Advancing Health and Wellness" (AHW), beginning with the CY 2026 performance period/2028 MIPS payment year. This proposed addition emphasizes CMS' priority of overall health promotion and addresses broader aspects of healthcare that go beyond the direct treatment of diseases.

We proposed to amend § 414.1355(c)(7) by adding a new subcategory, "Advancing Health and Wellness" (AHW), to replace the "Achieving Health Equity" subcategory. Our proposal to add the AHW subcategory for the improvement activities performance category will address gaps in MIPS eligible clinicians' involvement in preventive care and health promotion. Our goal for this new subcategory is to ensure that care is tailored to meet the needs of patients, including their mental health and chronic disease management and prevention.

As discussed in sections IV.A.4.d.(3)(b)(iii) and IV.A.4.d.(3)(b)(vii) of this final rule, we also proposed to reassign one existing improvement activity (IA_PM_13 "Chronic Care and Preventative Care Management for Empaneled Patients") to this new AHW subcategory. This activity allows a MIPS eligible clinician to manage chronic and preventive care for empaneled patients and would align with the "Advancing Health and Wellness" subcategory description. We will be adding more activities to this subcategory in future rulemaking.

We solicited public comments on the proposal to adopt a new subcategory, "Advancing Health and Wellness," to the improvement activities performance category and at § 414.1355(c)(7) beginning with the CY 2026 performance year/2028 MIPS payment year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the addition of the Advancing Health and Wellness subcategory. However, a commenter also recommended that we clearly define and establish how "well-being" will be measured before it is adopted as a formal requirement.

Response: We appreciate the commenter's request for clarification on how well-being may be measured within the Advancing Health and Wellness subcategory. "Well-being" is intended to reflect overall health status beyond the treatment of specific conditions. Measurement approaches can include patient-reported outcome measures, clinical indicators such as preventive service use or chronic condition management, and functional outcomes like improvements in mobility or daily activities. To support implementation, we added an improvement activity from the CMS inventory to this new subcategory. At this time, we are not prescribing a single definition of well-being but instead allowing flexibility for practices to demonstrate improvement through established improvement activities. We will continue to assess possible improvement activities and will consider additional refinements in future rulemaking.

After consideration of public comments, we are finalizing the addition of the Advancing Health and Wellness subcategory as proposed.

(iv) Adopt New Improvement Activities Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule (90 FR 32724), we proposed to adopt three new improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year. We proposed that the IA_PM_27 (Improvement Detection of Cognitive Impairment in Primary Care) and IA_PM_28 (Integrating Oral Health Care in Primary Care) activities will be included in the Population Management subcategory. We proposed that the IA_PSPA_34 (Patient Safety in Use of Artificial Intelligence [AI]) activity will be included in the Patient Safety and Practice Assessment subcategory.

The first new improvement activity, IA_PM_27, titled "Improving Detection of Cognitive Impairment in Primary Care," will allow MIPS eligible clinicians to increase the detection of cognitive impairment, especially in its early stages, by tracking baseline detection rates for mild cognitive impairment (MCI), dementia, and cognitive impairment. If rates are below 1.0, clinicians would increase Annual Wellness Visit uptake, ensure structured cognitive assessments, and address memory concerns during intake for patients 65+. Detection rates will be remeasured quarterly, with a focus on Medicare patients aged 65 and older. The second new improvement activity, IA_PM_28, titled "Integrating Oral Health Care in Primary Care," will allow MIPS eligible clinicians to include an oral health risk assessment and intraoral screening in primary care, educate patients on the importance of oral health, and provide counseling on its impact on systemic diseases. For patients without a dental home or those with oral health needs, a dental referral would be provided.

The third new improvement activity, IA_PSPA_34, titled "Patient Safety Use of Artificial Intelligence," will involve developing a new data-collection field within patient safety reporting systems for AI-attributable events. This will include events where actual harm was caused to a patient because AI technology was used, as well as near misses. Once a MIPS-eligible clinician has identified an event, a process to identify the cause and plan for future mitigation will be documented.

We refer readers to Table F-B1 in Appendix 2 of this final rule for more information regarding each of these proposed improvement activities.

We solicited public comments on proposals to add each of these activities to the improvement activities performance category beginning with the CY 2026 performance period/2028 MIPS payment year.

We received public comments on these proposals. The comments and responses may be found in

Appendix 2 of this final rule. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the addition of the three new improvement activities.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing the addition of three new improvement activities as proposed.

(v) Modify Existing Improvement Activities Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule (90 FR 32724 and 32725), we proposed to modify seven existing improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year. First, IA_AHE_1, IA_AHE_3, IA_AHE_6, IA_AHE_7, and IA_AHE_10, currently specified for the Achieving Health Equity subcategory, will be reassigned to other subcategories to better align each individual activity's purpose with its subcategory. We proposed to reassign IA_AHE_1 and IA_AHE_6 to the "Expanded Practice Access" (EPA) subcategory, IA_AHE_3 and IA_AHE_7 to the "Beneficiary Engagement" (BE) subcategory, and IA_AHE_10 to the "Patient Safety and Practice Assessment" (PSPA) subcategory. Second, we proposed to also reassign IA_PM_13, "Chronic Care and Preventative Care Management for Empaneled Patients," to the new "Advancing Health and Wellness" subcategory. Third, we proposed several modifications to IA_BMH_1, currently titled "Diabetes Screening." Specifically, we proposed to expand the scope of the activity. Currently, IA_BMH_1 is focused on screening only diabetic patients taking anti-psychotic medications.

The proposed modifications to IA_BMH_1 would broaden the relevant patient population by requiring a comprehensive physical health screening on all patients taking anti-psychotic medications. This modified activity will encompass a broader range of health conditions, beyond just diabetes, that may be impacted by antipsychotic medications. While diabetes remains a key focus due to its significant association with antipsychotic use, the expanded title reflects the inclusion of additional monitoring components, such as obesity, hypertension, dyslipidemia, movement disorders (for example, tardive dyskinesia), and other relevant physical health conditions. Diabetes would remain relevant for this improvement activity as it is a major comorbidity linked to antipsychotic medications, and monitoring for

diabetes will remain an integral part of the comprehensive health assessment for these patients under this activity. We also proposed to modify the title of IA_BMH_1, renaming it to "Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring." This proposed title better reflects the substantive modifications we proposed for this activity.

We refer readers to Table F-B2 in Appendix 2 of this final rule for more information regarding each of these proposed modifications to existing improvement activities.

We solicited public comments on our proposals to modify each of these activities currently specified for the improvement of activities performance category beginning with the CY 2026 performance period/2028 MIPS payment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the title modification of IA_BMH_1 but requested more clarity around the activity's requirements. One commenter stated that there were discrepancies between the rationale, which references comprehensive physical health screenings, and the proposed activity description, which instead focuses on implementing process improvements unrelated to screenings.

Response: We appreciate the support for the proposed title modification of IA_BMH_1. We will seek to address any discrepancies in the validation criteria for this modified activity for CY 2026. This will list the criteria used to audit and validate data submitted for MIPS performance categories and will provide guidance on what is expected for each improvement activity to be considered complete. Validation criteria for CY 2025 can be found at https://qpp.cms.gov/mips/improvement-activities.

After consideration of public comments, we are finalizing all improvement activity modifications as proposed.

(vi) Remove Existing Improvement Activities Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule (90 FR 32725), we proposed to remove eight previously finalized improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year: IA_AHE_5, IA_AHE_8, IA_AHE_9, IA_AHE_11, IA_AHE_12, IA_PM_6, IA_PM_26, and

IA_ERP_3. We proposed removal of these specific improvement activities in accordance with our activity removal policy set forth at § 414.1355(d). Specifically, we proposed to remove each of these eight improvement activities under Removal Factor 7, which provides that we may remove an improvement activity if we determine it is obsolete (§ 414.1355(d)(7)). When we codified this Removal Factor at § 414.1355(d)(7) in the CY 2025 PFS final rule (89 FR 98408 and 98409), we stated that, when we originally established this removal factor, we employed a commonly used definition of "obsolete" as in 'out of date' (89 FR 98409). We further stated that, in the context of the Quality Payment Program, this means an activity that no longer reflects current clinical best practices, that is no longer available for implementation (for example, when a program or initiative upon which an activity depends has been ended or closed), and/or that, because of the nature of the activity, cannot be attested to year after year with a reasonable expectation of clinical quality improvement year after year (89 FR 98409).

We proposed to remove these activities to evolve the Improvement Activities Inventory and emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Factor 7, Activity is obsolete, supports our proposals to remove these activities as they do not reflect CMS' current prioritization of best clinical practices emphasizing holistic, coordinated, and data-driven approaches to care improvement. CMS' quality strategy and clinical standards have evolved to emphasize proactive, whole-person approaches to care, including prevention, behavioral health integration, and coordinated management of chronic conditions. Our proposal to remove IA_ERP_3 would also align with recent FDA and CDC guidance regarding updating vaccination recommendations and expiration of the PHE for COVID-19.[434,435] We refer readers to Table F-B3 in Appendix 2 of this final rule for more information regarding our proposals to remove each of these existing improvement activities.

We solicited public comments on our proposals to remove each of these activities from the improvement activities performance category beginning with the CY 2026 performance period/2028 MIPS payment.

We received public comments on these proposals. The following is a summary of the comments

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[434] https://www.nejm.org/doi/full/10.1056/NEJMsb2506929?logout=true.
[435] https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/your-health/end-of-phe.html.

we received and our responses.

Comment: Most commenters opposed the removal of eight related improvement activities, stating that doing so could weaken progress toward inclusive, equitable care. A few commenters who opposed the proposal to remove the Achieving Health Equity subcategory stated that the removal of eight measures from the subcategory do not meet the criteria for removal under the "obsolete" designation, as they reflect current clinical best practices and were intentionally adopted to support improved patient health outcomes and advance whole-population health.

Response: Although we acknowledge the commenters' responses, we determined that these eight improvement activities meet the criteria for removal under the "obsolete" removal criterion. We refer to the previous section which explains our reasoning for these removals.

Comment: A few commenters suggested maintaining or reclassifying IA_AHE_9, the only nutrition-focused activity, to ensure continued attention to food insecurity and nutrition risk.

Response: While we acknowledge the importance of nutrition, this specific improvement activity is not fully aligned with the Agency's priorities of health, wellness, and prevention, although we do take note of this improvement activity's elements that can be integrated into the new health and wellness framework. As part of ongoing efforts to align MIPS Improvement Activities with CMS' broader strategic priorities, we are refining the Inventory to focus on activities that promote whole-population health. This approach emphasizes prevention, wellness, and outcomes that benefit all patients across care settings, rather than initiatives targeted toward specific subpopulations, such as IA_AHE_9 does. We thank the commenters for their suggestions, as proper nutrition is fundamental to maintaining health, preventing chronic disease, and supporting resilience. We may consider how we can elevate nutrition as part of a broader wellness agenda for possible nutrition-oriented improvement activities in future rulemaking.

After consideration of public comments, we are finalizing the removal of the eight improvement activities as proposed.

(4) MIPS Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A)(iv) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the MIPS Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category).

Section 1848(q)(2)(B)(iv) of the Act provides that the requirements established under section 1848(o)(2) of the Act for determining whether a MIPS eligible clinician is a meaningful EHR user also apply to our assessment of a MIPS eligible clinician's performance on measures and activities with respect to the MIPS Promoting Interoperability performance category. Section 1848(o)(2)(D) of the Act generally provides that the requirements for being a meaningful EHR user under section 1848(o)(2) continue to apply for purposes of the MIPS Promoting Interoperability performance category.

Under section 1848(o)(2)(A) of the Act, a MIPS eligible clinician must meet three requirements related to the meaningful use of CEHRT during a performance period for a MIPS payment year. Specifically, under section 1848(o)(2)(A) of the Act, the MIPS eligible clinician must: (1) demonstrate to the satisfaction of the Secretary the use of CEHRT in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary; (2) demonstrate to the satisfaction of the Secretary that their CEHRT is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for electronic exchange of health information to improve the quality of care, such as promoting care coordination, and demonstrates (through a process specified by the Secretary, such as use of an attestation), that they have not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the CEHRT; and (3) use CEHRT to submit information on clinical quality measures and such other measures as selected by the Secretary.

For our previously established policies regarding the MIPS Promoting Interoperability performance category, we refer readers to regulations at §§ 414.1375 and 414.1380(b)(4) and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820),

CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), CY 2023 PFS final rule (87 FR 70060 through 70087), CY 2024 PFS final rule (88 FR 79308 through 79312 and 88 FR 79351 through 79365), the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule (89 FR 54662 through 54718), and CY 2025 PFS final rule (89 FR 98414 through 98427).

In the CY 2026 PFS proposed rule, we proposed to:

- Modify the Security Risk Analysis measure to include a second component requiring an affirmative attestation of having conducted security risk management in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule;
- Modify the High Priority Practices Safety Assurance Factors for Electronic Health Record (EHR) Resilience (SAFER) Guide Measure by requiring an affirmative attestation of completing an annual self-assessment using the SAFER Guides published in January of 2025; and
- Adopt the Public Health Reporting Using Trusted Exchange Framework and Common Agreement™ (TEFCA™) measure as an optional bonus measure under the Public Health and Clinical Data Exchange objective.
- Rectify an incongruency by amending regulation at § 414.1380(b)(4)(ii)(C) to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, the total number of bonus points available to be earned when reporting one bonus measure, more than one bonus measure, or all bonus measures is a total of five bonus points for the MIPS Promoting Interoperability performance category.

For both the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, we proposed to--

- Adopt and codify at § 414.1380(b)(4)(iii) and § 495.24(f)(3), respectively, a measure suppression policy beginning with the CY 2026 performance period/2028 MIPS payment year and the EHR reporting period in CY 2026; and

- Suppress the Electronic Case Reporting measure by excluding the measure from scoring for MIPS eligible clinicians for the CY 2025 performance period/2027 MIPS payment year and eligible hospitals and critical access hospitals (CAHs) for the EHR reporting period in CY 2025.

(b) Definition of Certified EHR Technology

In accordance with § 414.1375(b)(1), to earn a performance category score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician must be a meaningful EHR user for MIPS and use CEHRT during the performance period, as both terms are defined in § 414.1305. In the CY 2025 PFS final rule, we discussed modifications we had previously finalized related to the CEHRT definition for the Quality Payment Program (QPP), including for the MIPS Promoting Interoperability performance category, at § 414.1305 (89 FR 98414 and 98415). Currently, we define CEHRT, for purposes of MIPS, as EHR technology (which could include multiple technologies) certified under the Office of National Coordinator for Health Information Technology's (ONC)[436] Health Information Technology (IT) Certification Program that meets the Base EHR definition at 45 CFR 170.102 and is certified as meeting additional ONC health IT certification criteria as adopted and updated in 45 CFR 170.315 as enumerated in paragraph (2) of the CEHRT definition at § 414.1305, including as necessary to report on applicable objectives and measures specified for MIPS. We provide Table C-G5 in this final rule, which sets forth the objectives and measures for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. Given the central role of using CEHRT that meets this definition at § 414.1305 for purposes of earning a score for the MIPS Promoting Interoperability performance category, we highlight recent updates to the ONC Health IT Certification Program's certification criteria.

In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) final rule (89 FR 1236 through 1238), ONC adopted the certification criterion, "decision support interventions (DSI)" at 45 CFR 170.315(b)(11) to replace the "clinical decision support (CDS)" certification criterion at 45 CFR 170.315(a)(9), the latter of which is

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[436] On July 29, 2024, notice was posted in the Federal Register that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903). We will continue to refer to ONC in historical actions prior to this date and in actions involving the ONC Health IT Certification Program. We will otherwise use ASTP/ONC to refer to the office.

included in the Base EHR definition 45 CFR 170.102 until December 31, 2024. HTI-1's finalized DSI criterion at 45 CFR 170.315(b)(11) requires that Health IT Modules must, among other functions, enable a limited set of identified users to select (that is, activate) evidence-based DSIs and Predictive DSIs (as defined at 45 CFR 170.102)[437] and support "source attributes"[438]—categories of technical performance and quality information—for both evidence-based and Predictive DSIs. Further, ONC finalized that a Health IT Module may meet the Base EHR definition by either being certified to the existing CDS version of the certification criterion at 45 CFR 170.315(a)(9) or being certified to the revised DSI criterion at 45 CFR 170.315(b)(11), for the period up to, and including, December 31, 2024. On and after January 1, 2025, ONC finalized that only the DSI criterion at 45 CFR 170.315(b)(11) is included in the Base EHR definition (89 FR 1281). ONC further finalized that the adoption of the CDS criterion at 45 CFR 170.315(a)(9) expired on January 1, 2025 (89 FR 1281).

In addition to the DSI criterion, to which Health IT Modules must be certified to meet the Base EHR definition after January 1, 2025, ONC finalized other updates in the HTI-1 final rule, for which health IT developers must update and provide Health IT Modules to their customers by January 1, 2026. These include updates resulting from the following finalized policies:

- The "[t]ransmission to public health agencies—electronic case reporting" criterion at 45 CFR 170.315(f)(5) was updated to specify consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace functional, descriptive requirements in the existing criterion (89 FR 1226). We have identified this criterion as required for the Electronic Case Reporting measure. We note that on July 31, 2025, ONC issued a notice of enforcement discretion regarding these new standards-based requirements, which remains in effect.[439]

- The United States Core Data for Interoperability (USCDI) version 3 was adopted at 45 CFR 170.213(b), and ONC finalized that USCDI version 1 at 45 CFR 170.213(a) will expire on January 1, 2026. This change impacts several ONC health IT certification criteria that reference the USCDI, including the "transitions of care" certification criterion at 45 CFR 170.315(b)(1), the "Clinical

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[437] 45 CFR 170.315(b)(11)(iii)(A) and (B).
[438] 45 CFR 170.315(b)(11)(iv)(A) and (B).
[439] Office of the National Coordinator for Health IT, Electronic Case Reporting Certification Criterion Enforcement Discretion Notice located at: https://www.healthit.gov/topic/electronic-case-reporting-certification-criterion-enforcement-discretion-notice.

information reconciliation and incorporation—Reconciliation" certification criterion at 45 CFR 170.315(b)(2) and the "View, download, and transmit to 3rd party" certification criterion at 45 CFR 170.315(e)(1) (89 FR 1214). The "transitions of care" certification criterion at 45 CFR 170.315(b)(1) is included in the "Base EHR definition" while the "Clinical information reconciliation and incorporation—Reconciliation" certification criterion at 45 CFR 170.315(b)(2) is required for the "Support Electronic Referral Loops by Receiving and Reconciling Health Information" measure and the "View, download, and transmit 3rd party" certification criterion is required for the "Provide Patients Electronic Access to their Health Information" measure. We note that on March 21, 2025, ONC issued a notice of enforcement discretion regarding implementation of USCDI version 3, which remains in effect.[440]

- The "standardized application programming interface (API) for patient and population services" certification criterion at §170.315(g)(10), which is included in the Base EHR definition, was modified to include newer versions of certain standards (including USCDI version 3) and updated functionality to support the criterion (89 FR 1283 through 1295).

We refer readers to the HTI-1 final rule (89 FR 1192) and resources available on the ASTP/ONC website for complete information regarding the updates to ONC health IT certification criteria.[441]

Lastly, in the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization (HTI-4) final rule (90 FR 36541 and 36542), published as part of the FY 2026 IPPS/LTCH final rule, ASTP/ONC finalized a subset of new and revised standards and ONC health IT certification criteria proposed in the HTI-2 proposed rule for the ONC Health IT Certification Program, including the following policies:

- ASTP/ONC updated the "electronic prescribing" certification criterion in 45 CFR 170.315(b)(3) to incorporate National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011, require support for electronic prior authorization transactions in accordance with this standard, and revise other elements of the criterion. We have identified the use of health IT certified to this criterion as required for the Electronic Prescribing measure. ASTP/ONC finalized that

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[440] Office of the National Coordinator for Health IT, USCDI v3 Data Elements Enforcement Discretion Notice, located at: https://www.healthit.gov/topic/uscdi-v3-data-elements-enforcement-discretion-notice.

[441] For more information, visit: *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

health IT developers must update Health IT Modules certified to the "electronic prescribing" criterion by January 1, 2028.

- ASTP/ONC finalized the adoption of a "real-time prescription benefit" certification criterion in 45 CFR 170.315(b)(4), in order to implement section 119(b)(3) of Title I of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260). ASTP/ONC finalized the inclusion of this certification criterion in the Base EHR definition in 45 CFR 170.102 after January 1, 2028.

- ASTP/ONC finalized a set of three health IT certification criteria (at 45 CFR 170.315(g)(31), (32), and (33)) focused on electronic prior authorization and adopted a set of HL7 FHIR IGs developed by the HL7 Da Vinci Project[442] to support these criteria. ASTP/ONC finalized these criteria to make available Health IT Modules that can enable health care providers to conduct prior authorization transactions using payer APIs established in the CMS Interoperability and Prior Authorization final rule (89 FR 8858 through 8871). Use of such Health IT Modules will support MIPS eligible clinicians required to report on the Electronic Prior Authorization measure for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year, as well as eligible hospitals and critical access hospitals required to report on the Electronic Prior Authorization measure for the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2027.

We refer readers to section IV.A.4.d.(4)(i). of this final rule, the HTI-4 final rule (90 FR 36541), and resources available on the ASTP/ONC website for complete information regarding the updates to ONC Health IT Certification Program.[443]

(c) Modification to the Security Risk Analysis Measure

(i) Background

The HIPAA Security Rule[444] (45 CFR part 160 and subparts A and C of part 164) contains, among other things, the administrative safeguards that covered entities and business associates (45 CFR 160.103) must be implemented, such as the standard and implementation specifications for

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[442] For more information about the HL7 Da Vinci Project, *see*: https://www.hl7.org/about/davinci/index.cfm.

[443] For more information, visit: *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

[444] The U.S. Department of Health and Human Services has proposed to modify the HIPAA Security Rule to strengthen the cybersecurity of electronic protected health information, including proposals to revise the existing requirements to conduct a risk analysis and risk management. *See generally* HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule (90 FR 898).

security management processes. Among those safeguards are implementation specifications that require covered entities and business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by the covered entity or business associate (45 CFR 164.308(a)(1)(ii)(A)) and to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306(a) and the risk management requirements at 45 CFR 164.308(a)(1)(ii)(B).

For MIPS eligible clinicians, ensuring the privacy and security of ePHI is essential for demonstrating meaningful use of CEHRT as discussed in the CY 2026 PFS proposed rule (90 FR 32727). In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program final rule (Stage 1 final rule) (75 FR 44368 through 44369), the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2 final rule (Stage 2 final rule) (77 FR 54002 and 54003), and the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (Stage 3 final rule) (80 FR 62793 through 62794), we discussed the benefits of safeguarding electronic health information and our determination that protecting electronic health information is essential to all other aspects of meaningful use. In the Stage 1 final rule, we noted that, while CEHRT provides tools for protecting health information, processes and possibly tools outside the scope of CEHRT are required (75 FR 44369). In the Stage 2 final rule, we also noted that unintended, unlawful, or both disclosures of protected health information could diminish individuals' confidence in EHRs and electronic health information exchange; ensuring that health information is adequately protected and secured will assist in addressing the unique risks and challenges that may be presented by EHRs (77 FR 54002). On these bases, we adopted and maintained the Security Risk Analysis measure based on the HIPAA Security Rule risk analysis requirement at 45 CFR 164.308(a)(1)(ii)(A) for the Medicare EHR Incentive Program for Eligible Professionals, the predecessor to the MIPS Promoting Interoperability performance category.[445] Additional information on the initial

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[445] Section 101(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) sunset the Medicare EHR Incentive Program for Eligible Professionals, set forth at section 1848(o) of the Act. As discussed previously, section 1848(o)(2) of the Act has been incorporated into the MIPS Promoting Interoperability performance category's requirements via section 1848(q)(2)(B)(iv) of the Act. *See* CY 2017 Quality Payment Program final rule (81 FR 77018 and 77019) for more information regarding the sunsetting of the Medicare EHR Incentive Program for Eligible Professionals.

adoption of this measure can be found in prior rulemaking for the predecessor Medicare EHR Incentive Program for Eligible Professionals, including the Stage 1 final rule (75 FR 44369), Stage 2 final rule (77 FR 54002 and 54003), and Stage 3 final rule (80 FR 62793 through 62794). In the CY 2017 Quality Payment Program final rule, we adopted the Protect Patient Health Information objective for the MIPS Promoting Interoperability performance category and included the Security Risk Analysis measure within this objective (81 FR 77219 through 77220). We subsequently modified this measure in the CY 2019 PFS final rule (83 FR 59789 and 59790).

To earn a score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician must attest "Yes" or "No" as to whether they have conducted or reviewed a security risk analysis as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A) during the year in which the performance period occurs. MIPS eligible clinicians must attest "Yes" to the measure to be considered a meaningful EHR user. The measure is not scored individually at § 414.1380(b)(4)(ii) and does not contribute to the MIPS eligible clinician's MIPS Promoting Interoperability performance category score for the Protect Patient Health Information objective and measures. An attestation of "No" demonstrates that the MIPS eligible clinician did not complete the actions included in the measure as required by § 414.1375(b)(2)(ii)(A) and did not satisfy the definition of a meaningful EHR user at § 414.1305. Therefore, if the MIPS eligible clinician submits a "No" attestation for this measure, they would not earn a score for the MIPS Promoting Interoperability performance category, resulting in a score of zero, in accordance with § 414.1375(b)(2). We refer readers to Tables C-G2 and C-G3 in the CY 2026 PFS proposed rule for more information regarding the proposed measures and scoring methodology for the MIPS Promoting Interoperability performance category, including the Security Risk Analysis measure (90 FR 32737 through 32744).

(ii) Modification to the Security Risk Analysis Measure Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

While the Security Risk Analysis measure currently requires MIPS eligible clinicians to attest to conducting a security risk analysis as required under the HIPAA Security Rule, the Security Risk Analysis measure does not currently require MIPS eligible clinicians to manage their security risk or attest to having implemented security measures to manage their security risk. Codified at 45 CFR

164.308(a)(1)(ii)(B), the HIPAA Security Rule implementation specification for risk management requires the implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306(a). The HIPAA Security Rule does not prescribe a specific methodology for conducting a risk analysis or managing risk (45 CFR 164.308(a)(1)(ii)(A) and (B)). We refer readers to the Security Risk Assessment Tool (*https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool*) developed by ASTP/ONC in collaboration with the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR), and OCR's cybersecurity newsletters and other risk analysis materials[446] for educational resources on conducting a security risk assessment as required by the HIPAA Security Rule. Additional information is also available in the National Institute of Standard and Technology (NIST) special publication, *Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule: A Cybersecurity Resource Guide*.[447]

In the CY 2026 PFS proposed rule, we proposed to modify the existing Security Risk Analysis measure to add a second attestation, requiring MIPS eligible clinicians to attest "Yes" to having implemented security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level such that they are compliant with 45 CFR 164.306(a) as required by the HIPAA Security Rule implementation specification for risk management (90 FR 32727 and 32728). This second attestation would be in addition to the current requirement under the measure for MIPS eligible clinicians to attest "Yes" to having conducted or reviewed a security risk analysis. With the modification to this measure, MIPS eligible clinicians would be required to submit two affirmative ("Yes") attestations to comply with § 414.1375(b)(2)(ii)(A), in which they have: (1) conducted or reviewed a security risk analysis as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A); and (2) conducted security risk management activities as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(B), specifically the implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306. Also, we proposed to modify the measure specifications to better align with the requirements of the HIPAA Security Rule.

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[446] U.S. Department of Health and Human Services, Office of Civil Rights newsletters and risk analysis materials located at: *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html.*
[447] *See* NIST SP 800-66, rev. 2, located at: *https://csrc.nist.gov/pubs/sp/800/66/r2/final.*

The proposed modifications to the Security Risk Analysis measure would increase accountability among MIPS eligible clinicians who have not taken steps to reduce risks and vulnerabilities to ePHI and would provide transparency regarding the efforts of MIPS eligible clinicians that are already taking steps to manage this risk. Furthermore, the proposal is in alignment with the finalized modification to the Security Risk Analysis measure in the Medicare Promoting Interoperability Program (90 FR 37045 through 37048).

To reflect the proposed addition of the security risk management component, we proposed the modified measure would read as follows: First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the HIPAA Security Rule requirements at 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include addressing the security of data created or maintained by CEHRT (*to include encryption*), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the MIPS eligible clinician would adopt an equivalent alternative measure if it is reasonable and appropriate to do so.

To meet the requirements of the modified Security Risk Analysis measure, we proposed that MIPS eligible clinicians would be required to separately attest "Yes" to both components of the modified measure, specifically attest "Yes" that they have met the existing security risk analysis requirement component, *and* attest "Yes" that they have met the security risk management component to be considered a meaningful EHR user beginning with the CY 2026 performance period/2028 MIPS payment year.

We did not propose modifications to the timeframe regarding when a MIPS eligible clinician must complete the actions specified for the Security Risk Analysis measure as currently provided at § 414.1375(b)(2)(ii)(A). As set forth at § 414.1375(b)(2)(ii)(A), a MIPS eligible clinician may attest "Yes" regarding their completion of the actions included in this measure so long as they complete the required actions any time during the calendar year in which the performance period occurs.

Also, we did not propose modifications to the current scoring methodology for the Security Risk Analysis measure, as described in section IV.A.4.d.(4).(h).(ii). of this final rule. To meet the

requirements of the MIPS Promoting Interoperability performance category, MIPS eligible clinicians will need to affirmatively ("Yes") attest to the two components of the measure; otherwise, MIPS eligible clinicians will receive a score of zero for the entire MIPS Promoting Interoperability performance category. If a MIPS eligible clinician attests "No" to not completing the risk analysis component, the risk management component, or both components, or did not report the measure, then they will fail to earn a score for the MIPS Promoting Interoperability performance category (and receive a score of zero) as currently provided at § 414.1375(b)(2)(ii)(A).

We solicited public comment on the proposal to modify the Security Risk Analysis measure beginning with the CY 2026 performance period/2028 MIPS payment year. Also, we solicited public comment regarding compliance with the security risk management requirements and the potential impact the proposed modification to the Security Risk Analysis measure would have on risk management compliance and any potential burden from the proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to modify the Security Risk Analysis measure. A few commenters indicated that requiring MIPS eligible clinicians to attest to having conducted security risk management activities in addition to security risk analysis strengthens cybersecurity preparedness and aligns with the HIPAA Security Rule. A few commenters stated that the proposal provides an appropriate balance between safeguarding patient data and minimizing mandatory reporting requirements without increasing burden.

Response: We appreciate the support from commenters regarding the proposal to modify the Security Risk Analysis measure. We agree that adding the security risk management attestation requirement to the Security Risk Analysis measure aligns with the HIPAA Security Rule and would assist MIPS eligible clinicians in strengthening their cybersecurity preparedness. Also, we agree that the change to the Security Risk Analysis measure will increase accountability for reducing risks and vulnerabilities to ePHI while balancing the need to safeguard patient data with minimal reporting requirements.

Comment: A commenter expressed support of the proposal by noting that the measure requirements could cover software that is not certified under the ONC Health IT Certification Program,

and that it could be a requirement to participate in QPP.

Response: We appreciate the support from the commenter.

Comment: Several commenters requested that CMS provide additional support or incentives for the implementation of security risk analysis and security risk management. A few commenters encouraged CMS and ASTP/ONC to provide fact sheets, guidance, and educational materials specific to security risk analysis and security risk management. Another commenter requested that CMS work with physician organizations to ensure that MIPS eligible clinicians receive the necessary education and training to ensure that they are complying with requirements and understand the distinction between the Security Risk Analysis measure and existing HIPAA Security Rule requirements.

Response: We note that the requirements of the Security Risk Analysis measure, including the security risk analysis activities and the security risk management activities, reflect requirements under the HIPAA Security Rule; the Security Risk Analysis measure does not create additional requirements beyond the scope of the HIPAA Security Rule requirements. OCR has developed many resources such as guidance materials, trainings, videos, tools, frequently asked questions, and newsletters to support implementation and compliance of security risk analysis and management activities.[448] ONC and OCR developed the HIPAA Security Risk Assessment Tool,[449] which includes features that make it useful in assisting small and medium-sized practices and business associates perform a risk assessment.

Comment: A few commenters expressed concerns regarding the expansion of the Security Risk Analysis measure requirements and associated burden. The commenters indicated that small, rural, and under-resourced MIPS eligible clinicians would experience financial and resource burden due to the implementation of security risk management. A commenter indicated that risk management activities would create burden for health systems and organizations with large numbers of hospitals and clinics.

Response: As covered entities and business associates under the HIPAA Security Rule, MIPS eligible clinicians are already required to conduct security risk management activities. We believe that the requirement to attest to having conducted security risk management activities will not result in undue burden to small and rural practices, or larger health systems or organizations.

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[448] U.S. Department of Health and Human Services, Office of Civil Rights, Security Rule Guidance Material located at: https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html?language=es.
[449] HIPAA Security Risk Assessment Tool located at: https://www.healthit.gov/providers-professionals/security-risk-assessment-tool.

Comment: A few commenters requested that CMS provide sufficient time for organizations to implement security risk management processes after performing a security risk analysis, citing concern that clinician practices may have difficulty implementing all changes identified during a risk assessment conducted within the same calendar year. Commenters recommended that MIPS eligible clinicians should be allowed to attest "Yes" in instances when a security risk management plan is in place, but implementation is in progress.

Response: We recognize that implementing security measures to manage risk often requires complex technical changes, organizational project management, and planned timelines. The presence of a risk management plan and a good faith effort to progress in implementing necessary risk management efforts is sufficient for a MIPS eligible clinician to attest "Yes" for the security risk management component of the Security Risk Analysis measure. MIPS eligible clinicians that conduct the security risk analysis in quarter 4 of the calendar year would therefore only need to create a risk management plan and begin the process of implementation of such plan during the calendar year in which the performance period occurs. We recognize that security risk analysis activities and risk management plan activities, including the creation of a plan, are often a continuous and iterative processes that occur throughout the calendar year. As long as both activities (conduct a security risk analysis and create a risk management plan) occur during the calendar year in which the performance period occurs, the requirements of the measure will be met.

Comment: Several commenters did not support the security risk analysis measure modification and expressed concern that the proposed modification is duplicative or unnecessarily burdensome because MIPS eligible clinicians are already required by the HIPAA Security Rule to conduct regular security risk analyses and address identified vulnerabilities. A few commenters expressed concern that a distinction between security risk analysis and security risk management adds complexity to the measure.

Response: As covered entities and business associates under the HIPAA Security Rule, MIPS eligible clinicians are already required to conduct security risk management activities. The addition of the security risk management component to the Security Risk Analysis measure is designed to complement the HIPAA Security Rule rather than introduce complexity by specifying separate requirements for protecting patient health information. Therefore, we do not agree that the requirement to attest "Yes" to

having conducted risk management activities creates an additional administrative or regulatory burden, introduces an additional compliance step other than attesting "Yes" or "No" once a year to CMS, adds significant technical or compliance complexity, or places MIPS eligible clinicians at additional financial risk. The security risk management attestation reflects a MIPS eligible clinician's acknowledgment of having performed activities that meet the requirements of the HIPAA Security Rule implementation specification for risk management at 45 CFR 164.308(a)(1)(ii)(B). The addition of the security risk management component augments our past efforts to incorporate security as a fundamental structural component for the meaningful use of CEHRT.

Regarding the comment pertaining to the distinction between security risk analysis and security risk management, we believe that such distinction is necessary given that activities associated with security risk analysis and security risk management differ. Security risk analysis refers to the process of assessing threats to the privacy and security of protected health information, whereas security risk management refers to the creation of a plan to address and remediate threats.

Comment: A commenter recommended that CMS consider a performance-based measure to allow CMS to differentiate MIPS eligible clinician performance rather than an unscored required attestation.

Response: We note that the purpose of the Security Risk Analysis measure is not to assess the degree of compliance with the HIPAA Security Rule nor to compare MIPS eligible clinicians to each other regarding such compliance. Rather, compliance with the HIPAA Security Rule represents a broad minimum set of requirements for all covered entities under HIPAA. Therefore, we believe it is appropriate for the Security Risk Analysis measure to remain as an unscored attestation at this time rather than a performance-based measure in the MIPS Promoting Interoperability performance category.

After consideration of public comments, we are finalizing, as proposed, the proposal to modify the Security Risk Analysis measure by requiring MIPS eligible clinicians to attest "Yes" to having conducted security risk management in addition to the current requirement of the measure requiring MIPS eligible clinicians to attest "Yes" to having conducted or reviewed a security risk analysis as required by the HIPAA Security Rule. The finalized measure with two components is as follows: First, conduct or review a security risk analysis; and second, conduct security risk management activities, in accordance with the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and

management activities include addressing the security of data created or maintained by CEHRT (*to include encryption*), in accordance with 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the MIPS eligible clinician would adopt an equivalent alternative measure if it is reasonable and appropriate to do so. Also, we note that in the FY 2026 IPPS/LTCH PPS final rule, we adopted such an update for the Security Risk Analysis measure under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (90 FR 37045 through 37048).

(d) Modification to the High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide Measure

(i) Background

The 2025 SAFER Guides are an evidence-based set of recommendations in the form of eight stand-alone, subject-oriented chapters (previously nine chapters comprising the 2016 SAFER Guides) that present the health IT community, including MIPS eligible clinicians that use health IT, with best practice recommendations to improve the safety and safe use of EHRs.[450] The SAFER Guides were first released in 2014 and updated in 2016. In the CY 2022 PFS final rule, we adopted the SAFER Guides measure under the Protect Patient Health Information objective in the MIPS Promoting Interoperability performance category beginning with the CY 2022 performance period/2024 MIPS payment year (86 FR 65475 through 65477). In the CY 2024 PFS final rule, we modified the requirements for the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year (88 FR 79354 through 79356), to require MIPS eligible clinicians to conduct, and attest ‘‘Yes,’’ to having completed an annual self-assessment using the High Priority Practices SAFER Guide. In the CY 2026 PFS proposed rule and this final rule, we refer to the measure as the “High Priority Practices SAFER Guide” measure given that the MIPS Promoting Interoperability performance category only requires MIPS eligible clinicians to affirmatively attest to having completed an annual assessment using the High Priorities Practices SAFER Guide rather than all SAFER Guides.

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[450] ASTP/ONC SAFER Guides located at: *https://www.healthit.gov/topic/safety/safer-guides.*

(ii) Modification to the High Priority Practices SAFER Guide Measure Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In January of 2025, ASTP/ONC published an updated set of SAFER Guides (hereafter referred to as the 2025 SAFER Guides) located at: *https://www.healthit.gov/topic/safety/safer-guides*. The 2025 SAFER Guides consist of eight guides organized into three broad groups of Foundational Guides, Infrastructure Guides, and Clinical Process Guides. All Guides have been revised and contain new recommendations as well as the comprehensive consolidation of recommendations that were similar and overlap in function or intent with the 2016 SAFER Guides. For example, the "System Configuration" and "System Interfaces" chapters have been consolidated into a single chapter titled, "System Management." The entirety of the content recommendations, bibliography, and implementation guidance have been organized into a comprehensive table, which promotes the adoption of best safety practices for health IT. This update represents the most comprehensive revision of the SAFER Guides since they were first released. Table C-G1 provides the titles of the various guides, and chapters within the guides, that collectively comprise the 2016 SAFER Guides and the 2025 SAFER Guides, respectively.

When we finalized requiring a "Yes" attestation to account for completion of the self-assessment in the CY 2024 PFS final rule, as opposed to allowing a "Yes" or "No" attestation, some commenters expressed concern that the 2016 SAFER Guides contained outdated references and did not reflect current practices (88 FR 79355 through 79357). Additionally, some commenters recommended that CMS and ONC review and make updates to the 2016 SAFER Guides, regarding data privacy protection and present-day safety practices (88 FR 79355 through 79357). In the CY 2026 PFS proposed rule, we proposed to modify the requirement of the High Priority Practices SAFER Guide measure to reference the updated 2025 version of the High Priority Practices SAFER Guide as a direct response to such concerns (90 FR 32729 through 32730). The 2025 version of the High Priority Practices SAFER Guide is updated and streamlined to focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience.

TABLE C-G1: COMPARISON OF THE 2016 SAFER GUIDES AND THE 2025 SAFER GUIDES

Category	2016 SAFER Guides	2025 SAFER Guides
Foundational Guides	● High Priority Practices ● Organizational Responsibilities	● High Priority Practices ● Organizational Responsibilities
Infrastructure Guides	● Contingency Planning ● System Configuration ● System Interfaces	● Contingency Planning ● System Management
Clinical Process Guides	● Patient Identification ● Computerized Provider Order Entry with Decision Support ● Test Results Reporting and Follow-Up ● Clinician Communication	● Patient Identification ● Computerized Provider Order Entry with Decision Support ● Test Results Reporting and Follow-Up ● Clinician Communication

We proposed to modify the High Priority Practices SAFER Guide measure, which currently requires MIPS eligible clinicians to attest "Yes" to completing an annual self-assessment, by specifying that MIPS eligible clinicians utilize the 2025 version of the High Priority Practices SAFER Guide beginning with the CY 2026 performance period/2028 MIPS payment year. At § 414.1375(b)(2)(ii)(D), to earn a score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician is required to submit an affirmative attestation regarding their completion of the annual self-assessment to meet the requirement of the High Priority Practices SAFER Guide measure during the year in which the performance period occurs. For the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians complete this annual self-assessment using the 2016 version of the High Priority Practices SAFER Guide. We proposed to modify this measure by requiring that MIPS eligible clinicians complete this annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide beginning with the CY 2026 performance period/2028 MIPS payment year.

We did not propose any modifications to the scoring methodology for this measure. To meet the requirements of the MIPS Promoting Interoperability performance category, MIPS eligible clinicians will need to affirmatively ("Yes") attest to meeting the requirement of the measure; otherwise, MIPS eligible clinicians will receive a score of zero for the entire MIPS Promoting Interoperability performance category. If a MIPS eligible clinician attests "No" because they have not completed an annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide, or did not report the measure, then they will fail to earn a score for the MIPS Promoting Interoperability performance category (and receive a score of zero) as currently provided at § 414.1375(b)(2)(ii)(D). We refer readers to the CY

2024 PFS final rule for further information regarding the High Priority Practices SAFER Guide measure and its requirements (88 FR 79354 through 79356).

Both the 2016 and the 2025 SAFER Guides are available on the ASTP/ONC website located at: *https://www.healthit.gov/topic/safety/safer-guides*. We encourage MIPS eligible clinicians to begin to familiarize themselves with the 2025 SAFER Guides.

We solicited public comment on the proposal to modify the High Priority Practices SAFER Guide measure by requiring MIPS eligible clinicians to conduct an annual self-assessment using the 2025 High Priority Practices SAFER Guide (instead of the 2016 version) at any point during the calendar year in which the performance period occurs, beginning with the CY 2026 performance period/2028 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to modify the High Priority Practices SAFER Guide measure requiring the use of the most recently updated 2025 version of the High Priority Practices SAFER Guide. Several commenters indicated that the 2025 version better reflects current practices in health IT and data protection as compared to the 2016 version.

Response: We appreciate the support from commenters regarding the modification to the High Priority Practices SAFER Guide measure that will require the use of the updated 2025 version of the High Priority Practices SAFER Guide. We agree that the 2025 version of the SAFER Guides has improved alignment with current data security, including cybersecurity practices, compared to the 2016 version of the SAFER Guides.

Comment: A few commenters requested clarification regarding which version of the High Priority Practices SAFER Guide would be acceptable to use for meeting the measure requirement for the CY 2025 performance period. The commenters inquired if MIPS eligible clinicians can voluntarily attest to using the 2025 version of the High Priority Practices SAFER Guide for the CY 2025 performance period before it becomes required starting with the CY 2026 performance period. The commenters indicated that such clarification would be important to ensuring consistent expectations for MIPS eligible clinicians and helping health IT vendors guide their customers appropriately.

Response: Please note that we did not propose changes to the High Priority Practices SAFER Guide measure for the CY 2025 performance period/2027 MIPS payment year in the CY 2026 PFS

proposed rule. For the CY 2025 performance period/2027 MIPS payment year, the High Priority Practices SAFER Guide measure requires affirmatively attesting ("Yes") to completing an annual self-assessment using the 2016 version of the High Priority Practices SAFER Guide. In regard to the comments inquiring about the possibility of being able to voluntarily attest to completing an annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide for the CY 2025 performance period/2027 MIPS payment year, we believe that providing the availability of two different reporting options for the same measure may cause confusion regarding the reporting requirements for the High Priority Practices SAFER Guide measure. Beginning with the CY 2026 performance period/2028 MIPS payment year, the use of the 2025 version of the High Priority Practices SAFER Guide will be required for affirmatively attesting ("Yes") to completing an annual self-assessment. MIPS eligible clinicians can begin to familiarize themselves with the 2025 SAFER Guides, specifically the High Priority Practices SAFER Guide during CY 2025. We believe that allowing a full calendar year for MIPS eligible clinicians to review the 2025 version of the High Priority Practices SAFER Guide will allow for the uniform utilization beginning with the CY 2026 performance period/2028 MIPS payment year and subsequent years. Both the 2016 and the 2025 SAFER Guides are available on the ASTP/ONC website located at: https://www.healthit.gov/topic/safety/safer-guides.

Comment: A few commenters expressed concern regarding the reporting and implementation burden of the proposal by requiring the 2025 version of the High Priority Practices SAFER Guide beginning with the CY 2026 performance period/2028 MIPS payment year, particularly for MIPS eligible clinicians with limited resources. A few commenters requested that CMS make the High Priority Practices SAFER Guide measure voluntary. A few commenters recommended that CMS allow delaying the requirement of the use of the 2025 version of the High Priority Practices SAFER Guide measure for MIPS Promoting Interoperability performance category reporting. A commenter recommended that CMS reduce the administrative burden for clinical practices by shifting from an annual reporting schedule to a less frequent reporting interval. Another commenter suggested that CMS collaborate with vendors to enact periodic assessments of the burden and effectiveness of using the SAFER Guides while also exploring alternative options to assess organizational health IT capabilities. A commenter expressed the importance of having streamlined tools and education materials to help MIPS eligible clinicians with

limited resources use the 2025 version of High Priority Practices SAFER Guide self-assessment more effectively.

Response: While we acknowledge the concerns expressed by commenters regarding the potential burden or resource constraints from completing the self-assessment, we reiterate that the 2025 SAFER Guides have been updated and streamlined to focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes. We reiterate that the High Priority Practices SAFER Guide measure only requires that MIPS eligible clinicians attest "Yes" to having conducted an annual self-assessment using the High Priority Practices SAFER Guide; there are no requirements to meet a specific implementation status or implement any specific practices identified in the self-assessment. We defer to eligible MIPS clinicians to determine if they should adopt specific best practices contained within the SAFER Guides. We believe that there is value in completing a self-assessment using the High Priority Practices SAFER Guide. We, therefore, disagree that this measure update would introduce administrative burden, particularly for MIPS eligible clinicians with limited resources, given that a substantial portion of the information between the 2016 and 2025 versions of the High Priority Practices SAFER Guide remain the same.

We do not agree with commenters' suggestions to reduce the frequency of requiring the completion of an annual self-assessment. The High Priority Practices SAFER Guide measure only requires that MIPS eligible clinicians complete an annual self-assessment at any point during the calendar year in which the measure reporting period occurs. Additionally, we anticipate that the burden of completing an annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide could be reduced after the completion of an initial self-assessment if a given EHR configuration does not substantially change in a subsequent calendar year. We are committed to obtaining feedback from all interested parties through the rulemaking process regarding modifications to the High Priority Practices SAFER Guide measure and take into consideration the burden of completing an annual self-assessment using an updated version of the High Priority Practices SAFER Guide.

Regarding the comment pertaining to the availability of educational resources and materials to assist MIPS eligible clinicians with the completion of an effective annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide, the 2025 High Priority Practices Guide includes an

extensive set of references offering additional information and evidence. The 2025 SAFER Guides are located on the ASTP/ONC website at https://www.healthit.gov/topic/safety/safer-guides. Additionally, there are public resources available to MIPS eligible clinicians regarding conducting a self-assessment using the SAFER Guides such as a journal article entitled, ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides" (located at: https://jamanetwork.com/journals/jama/article-abstract/2788984).

Comment: A few commenters requested that the High Priority Practices SAFER Guide measure remain voluntary until CMS has enacted an assessment that establishes the efficacy of the SAFER Guides in improving EHR safety in care delivery settings for MIPS eligible clinicians.

Response: We note that the High Priority Practices SAFER Guide measure is a required measure, not voluntary, for the MIPS Promoting Interoperability performance category. The SAFER Guides, including the High Priority Practices SAFER Guide, are based on the available evidence from literature and consensus expert opinion. Subject matter experts in patient safety, informatics, quality improvement, risk management, human factors engineering, and usability collaborated to update the SAFER Guides. The SAFER Guides were reviewed by an external group of practicing clinicians, informaticians, and information technology professionals. The SAFER Guides can help identify potential risks, prioritize safety concerns, and implement strategies to mitigate those risks. Most importantly, the 2025 SAFER Guides were published largely in response to concerns that the 2016 SAFER Guides were outdated and no longer relevant (88 FR 59264 through 59265). Considering the rapid advancement of health IT, the information in the 2025 SAFER Guides reflects the current state of health IT practice.

Comment: A commenter expressed concern that the proposed modification to the High Priority Practices SAFER Guide measure is duplicative to the proposed modification to the Security Risk Analysis measure that adds a security risk management component, noting that both focus on the safety of the implementation and safe use of EHR technology.

Response: The High Priority Practices SAFER Guide measure and the Security Risk Analysis measure both aim to assess and enhance areas such as patient safety and security. However, there are notable differences. The SAFER Guides are a set of tools and recommendations focused on optimizing the safety and safe use of EHRs that help MIPS eligible clinicians identify and address potential risks by

providing a distinct framework to proactively identify and mitigate those risks. The High Priority Practices SAFER Guide specifically identifies "high risk" and "high priority" recommended safety practices that broadly address EHR safety concerns discussed in greater detail in the other SAFER Guides.[451] The High Priority Practices SAFER Guide self-assessment is useful and complementary to conducting a security risk analysis and development of a management plan, as all are necessary steps to ensuring EHR safety. The Security Risk Analysis measure and proposed modification, consistent with the HIPAA Security Rule requirements, involve a comprehensive assessment of all potential risks to the confidentiality, integrity, and availability of ePHI created or maintained by CEHRT and development of a management plan to address any identified risks. A self-assessment using the High Priority Practices SAFER Guide would not constitute a complete security risk analysis and management plan, nor would a security risk analysis and management plan constitute a self-assessment using the High Priority Practices SAFER Guide.

Comment: A commenter expressed concern regarding the High Priority Practices SAFER Guide measure's design as an attestation, noting that the design is not consistent with the Quality Payment Program's performance-based scoring design. Another commenter expressed appreciation that the measure remains as an attestation minimizing reporting burden.

Response: The purpose of this measure is not to assess the degree of compliance in implementing the High Priority Practices SAFER Guide, nor to compare MIPS eligible clinicians to each other. The High Priority Practices SAFER Guide measure only requires a MIPS eligible clinician attest to having completed an annual self-assessing using the 2025 version of High Priority Practices SAFER Guide and, thus, we believe it is appropriate for the High Priority Practices SAFER Guide measure to remain as an unscored attestation in the MIPS Promoting Interoperability performance category. We note that currently there is not a requirement to implement any recommendation contained within the 2025 High Priority Practices SAFER Guide.

After consideration of public comments, we are finalizing, as proposed, the proposal to modify the High Priority Practices SAFER Guide measure by requiring MIPS eligible clinicians to conduct an annual self-assessment using the 2025 version of the High Priority Practices SAFER Guide at any point

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[451] The 2025 SAFER Guides are available on the ASTP/ONC website located at *https://www.healthit.gov/topic/safety/safer-guides*.

during the calendar year in which the performance period occurs, beginning with the CY 2026 performance period/2028 MIPS payment year and subsequent years. Also, we note that in the FY 2026 IPPS/LTCH PPS final rule, we adopted a corresponding update for the SAFER Guides measure under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (90 FR 37049 through 37051).

(e) Public Health and Clinical Data Exchange Objective: Adoption of the Public Health Reporting Using the Trusted Exchange Framework and Common Agreement™ (TEFCA™) Measure as an Optional Bonus Measure Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

(i) Background

Under section 1848(o)(2)(A)(ii) of the Act, the MIPS Promoting Interoperability performance category encourages health information exchange, including for public health purposes through the Public Health and Clinical Data Exchange objective. Effective and efficient responses to public health events require rapid, accurate exchange of electronic health information between health care providers, and Federal, State, tribal, local, and territorial public health agencies (PHAs). Health care providers and MIPS eligible clinicians collect this electronic health information for patient care, and PHAs use the information for public health purposes such as tracking a disease, initiating contact tracing, or pinpointing the source of a disease or outbreak of foodborne illness.

Currently, there are 5 measures under the MIPS Promoting Interoperability performance category Public Health and Clinical Data Exchange objective: Immunization Registry Reporting, Electronic Case Reporting, Syndromic Surveillance Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. Two of the measures, Immunization Registry Reporting and Electronic Case Reporting, are required under the objective; 3 of the measures, Syndromic Surveillance Reporting, Public Health Registry Reporting and Clinical Data Registry Reporting, are optional bonus measures. MIPS eligible clinicians may receive a total of five bonus points for reporting on one or more optional measures.

Measures under the Public Health and Clinical Data Exchange objective promote the exchange of health information for specific public health use cases with PHAs and other entities using CEHRT. However, one difficulty with the electronic exchange of health information for many different public health purposes is that exchange between PHAs and MIPS eligible clinicians requires different processes

for each measure under the Public Health and Clinical Data Exchange objective. For instance, health information exchange for the Electronic Case Reporting measure may be based on several point-to-point connections among MIPS eligible clinicians, intermediaries, and PHAs, but these connections and agreements may be different for other use cases such as those associated with the Immunization Registry Reporting measure. TEFCA establishes a common governance and technical framework for nationwide health information exchange. We anticipated that participation in TEFCA could help reduce the difficulty of public health information exchange over time. Facilitating health information exchange with PHAs through the TEFCA framework has the potential to increase standardization of connections to PHAs and reduce reporting burden for MIPS eligible clinicians and PHAs.

(ii) Background on TEFCA

Section 4003(b) of the 21st Century Cures Act, enacted in 2016, amended section 3001(c) of the Public Health Service Act and required HHS to take steps to ensure full network-to-network exchange of health information. Specifically, in section 3001(c)(9)(A) of the Public Health Service Act, the Congress directed the National Coordinator, in collaboration with NIST and other agencies within HHS, to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally." Since the enactment of the 21st Century Cures Act, HHS has pursued development of the TEFCA framework.

The electronic exchange of health information allows MIPS eligible clinicians, other healthcare providers, and patients to access and securely share a patient's vital medical information electronically.[452] The framework of TEFCA standardizes health information exchange across many different networks, which further enables nationwide network-to-network exchange of health information. This standardization across networks simplifies health information exchange by reducing the number of connections that health care providers, MIPS eligible clinicians, PHAs, and other interested parties need to make to send and receive health information. TEFCA supports this standardization by creating baseline governance, legal, and technical requirements that enable secure health information exchange across different networks nationwide, including: a common method for authenticating trusted network

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[452] For additional information about health information exchange, visit: *https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-hie.*

participants, a common set of rules for trusted exchange, organizational and operational policies to enable the exchange of health information among networks, and a process for filing and adjudicating noncompliance with the terms of the Common Agreement.[453] We anticipate that TEFCA can help expand the nationwide availability of secure health information exchange capabilities in public health reporting.

CMS, the Centers for Disease Control and Prevention (CDC), and ASTP/ONC have been working closely with PHAs and other interested parties to expand the use of TEFCA for sharing health information for public health purposes. TEFCA is an important part of a shared vision for building a modernized public health infrastructure that connects previously siloed public health and health care systems. Early efforts to enable public health reporting through TEFCA exchange have focused on electronic case reporting, which is likely to be the primary mechanism of public health information exchange supported by entities that are part of TEFCA during CY 2026.

(iii) Adoption of Public Health Reporting Using TEFCA Measure as an Optional Bonus Measure Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule, we proposed to adopt an optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a PHA that occurs using TEFCA (the Public Health Reporting Using TEFCA measure) beginning with the CY 2026 performance period/2028 MIPS payment year (90 FR 32730 through 33732). Specifically, we proposed to adopt the following optional bonus measure:

- Public Health Reporting Using TEFCA. The MIPS eligible clinician must: (1) Participate as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on the ASTP/ONC website)[454]; (2) Not be suspended from participating in TEFCA Exchange; (3) Submit health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) Be in active engagement Option 2 (Validated Data Production) with a PHA

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[453] Additional information on TEFCA can be found on the ASTP/ONC website located at: *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

[454] See Common Agreement for Nationwide Health Information Interoperability Version 2.1 November 2024 located at: *https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf.*

to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) Use the functions of CEHRT to exchange with the PHA.

We proposed that a MIPS eligible clinician would be able to claim five bonus points under the Public Health and Clinical Data Exchange objective if the MIPS eligible clinician has attested that they are in active engagement Option 2 (Validated Data Production) with a PHA to submit electronic production data for one or more of the measures under the Public Health and Clinical Data Exchange objective using TEFCA. We refer readers to 90 FR 32730 through 33732 of the CY 2026 PFS proposed rule. As previously finalized in the CY 2023 PFS rule, for the measures in the Public Health and Clinical Data Exchange objective, MIPS eligible clinicians are required to report their level of active engagement as either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production), and may only spend one performance period at Option 1 (Pre-production and Validation) level of active engagement before advancing to Option 2 (Validated Data Production) to fulfill measure requirements (87 FR 70071 through 70074). Also, we proposed that this bonus measure would only be available where the MIPS eligible clinician is in active engagement Option 2 (Validated Data Production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective.

Furthermore, under the proposal, to attest "Yes" for the Public Health Reporting Using TEFCA measure, a MIPS eligible clinician must be a signatory to a Framework Agreement,[455] meaning either the Common Agreement or an agreement that includes the Participant/Sub-participant Terms of Participation,[456] and is not suspended under the respective agreement. Additionally, to attest "Yes" for such bonus measure, a MIPS eligible clinician must transmit electronic health information for at least 1 measure under the Public Health and Clinic Data Exchange objective using TEFCA.

For more information regarding the exchange of public health data using TEFCA, we refer readers to the TEFCA Public Health Exchange Purpose Implementation Standard Operating Procedure

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[455] The Common Agreement defines "Framework Agreement(s)" as: "any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable." *See* Common Agreement for Nationwide Health Information Interoperability Version 2.1 (Nov 2024) located at: *https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf.*

[456] Participant/Subparticipant Terms of Participation (Apr. 2024) located at: *https://rce.sequoiaproject.org/wp-content/uploads/2024/05/Common-Agreement-v2.0-Exhibit-1_508.pdf.*

(SOP).[457] The Public Health Exchange Purpose Implementation SOP currently identifies electronic case reporting and electronic laboratory reporting as exchange use cases, but the SOP can also be used for any allowable public health purpose. CMS, CDC, and ASTP/ONC are focused on establishing a foundation for MIPS eligible clinicians to use TEFCA to meet their public health reporting needs for the benefit of both public health and clinical care.

Finally, the MIPS eligible clinician must use the functions of CEHRT to engage in exchange with a PHA. We believe there are numerous certified health IT capabilities that can support exchange under a Framework Agreement with a PHA. For instance, MIPS eligible clinicians may exchange information under a Framework Agreement by using technology certified to the ONC health IT certification criterion, "Transmission to public health agencies — electronic case reporting" at 45 CFR 170.315(f)(5). This criterion is associated with the exchange use cases currently identified under the TEFCA Public Health Exchange Purpose Implementation SOP. We further recognize that MIPS eligible clinicians may connect to entities that connect directly or indirectly to a Qualified Health Information Network™ [458] (QHIN) using certified health IT in a variety of ways. This includes the other ONC health IT certification criterion at 45 CFR 170.315(f) associated with the Public Health and Clinical Data Exchange objective measures, and we believe that we should allow for substantial flexibility in how MIPS eligible clinicians use certified health IT to exchange health information under a Framework Agreement. We solicited public comment on the ONC health IT certification criteria that can support the proposed bonus measure.

We proposed that a MIPS eligible clinician may earn a total of five bonus points if the MIPS eligible clinician attests "Yes" to one, more than one, or all of the following optional bonus measures: the Public Health Reporting Using TEFCA measure, the Public Health Registry Reporting measure, the Clinical Data Registry Reporting measure, or the Syndromic Surveillance Reporting measure. In the CY 2022 PFS final rule, we previously finalized that, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians may attest "Yes" to more than one optional bonus measure in the Public Health and Clinical Data Exchange Objective, but the MIPS eligible clinician can only earn

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[457] For more information, visit: *https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-Public-Health-PH.pdf.*
[458] A Qualified Health Information Network is a health information network that facilitates TEFCA exchange by undergoing technology and security testing, onboarding, and designation. For more information, visit: *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

a total of five bonus points even if the MIPS eligible clinician attests "Yes" to multiple bonus measures (86 FR 65474 and 65475). As set forth in Table C-G3 in section IV.A.4.d.(4).(h).(i). of this final rule, we have specified optional bonus measures for only the Public Health and Clinical Data Exchange objective. We did not codify such policy in regulation at that time.

Currently, regulations at § 414.1380(b)(4) sets forth our scoring policy for bonus measures across all objectives in the MIPS Promoting Interoperability performance category, but does not clearly reflect the finalized policy as described in the CY 2022 PFS final rule (86 FR 86 FR 65474 and 65475). Specifically, regulations at § 414.1380(b)(4)(ii)(C) currently provide that, for the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth five points, as specified by CMS. Such language may imply that we will provide five points for performance of each individual optional measure; this language does not account for the maximum total of five bonus points scoring policy that was previously finalized in the CY 2022 PFS final rule (86 FR 65474 and 65475). In the CY 2023 PFS final rule (87 FR 70228), the current regulation codified at § 414.1380(b)(4) inadvertently did not reflect the intent of the allocation of bonus points for optional bonus measures as previously finalized (86 FR 86 FR 65474 and 65475). To rectify such incongruency beginning with the CY 2026 performance period/2028 MIPS payment year, we proposed to amend the regulation at § 414.1380(b)(4)(ii)(C) to address our previously finalized scoring methodology.

Specifically, we proposed to amend the regulation by adding a new paragraph at § 414.1380(b)(4)(ii)(C)*(3)* to provide that, beginning with the CY 2026 performance period/2028 MIPS payment year, the total number of bonus points available to be earned when reporting one bonus measure, more than one bonus measure, or all bonus measures is a total of five bonus points. We did not propose any substantive modifications to the remaining regulation text as currently codified at § 414.1380(b)(4)(ii)(C). We proposed technical modifications to reorganize the current regulation text as new paragraphs at § 414.1380(b)(4)(ii)(C)(*1*) and (C)(*2*).

Because the Public Health Reporting Using TEFCA measure would be an optional bonus measure, we did not propose any exclusions. Also, we proposed that if a MIPS eligible clinician uses TEFCA to fulfill any of the required Public Health and Clinical Data Exchange objective measures, such as Electronic Case Reporting or Immunization Registry Reporting that MIPS eligible clinician will be

able to claim the five bonus points if it affirmatively attests "Yes" to the Public Health Reporting Using TEFCA measure in addition to earning points for fulfilling the requirements of the required measure(s).

MIPS eligible clinicians can participate in TEFCA as Participants with a QHIN, or as Sub-participants through an entity such as a regional HIE or Health Information Network (HIN) that is a QHIN participant, through a health system, or through an EHR vendor.

We solicited public comment on the proposal to adopt the Public Health Reporting Using TEFCA measure as an optional bonus measure under the Public Health and Clinical Data Exchange objective beginning with the CY 2026 performance period/2028 MIPS payment year.

Also, we solicited public comment on the proposal to modify the regulation at § 414.1380(b)(4)(ii)(C) to clarify the scoring of optional bonus measures under the Public Health and Clinical Data Exchange objective beginning with the CY 2026 performance period/2028 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal for CMS to adopt the Public Health Reporting Using TEFCA measure as a new optional bonus measure under the Public Health and Clinical Exchange objective. Commenters indicated that this new measure would encourage and incentivize the adoption of TEFCA. A commenter noted that the proposed new optional bonus measure, Public Health Reporting Using TEFCA, aligns with adoption of the same optional bonus measure under the Medicare Promoting Interoperability Program.

Response: We appreciate the support from commenters regarding the proposal to adopt the Public Health Reporting Using TEFCA measure. The goal of the new Public Health Reporting Using TEFCA optional bonus measure is to encourage public health information exchange, technical modernization, and improved public health capacity. Also, the new Public Health Reporting Using TEFCA optional bonus measure will create further alignment between the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

Comment: A few commenters supported the proposal to adopt the Public Health Reporting Using TEFCA measure as an optional bonus measure, but expressed concern that the limited TEFCA adoption among PHAs may prevent many MIPS eligible clinicians from reporting the measure and attaining bonus points. Commenters noted that there is a lack of participation in TEFCA from state and local PHAs and

recommended that CMS work with ASTP/ONC to expand TEFCA's supported public health use cases. Also, commenters expressed concern that the presence of the new bonus measure may undermine the incentive to report on other public health bonus measures given that MIPS eligible clinicians cannot receive points for each bonus measure. A few commenters recommended that CMS allow MIPS eligible clinicians to receive more than five bonus points when reporting on multiple bonus measures in the Public Health and Clinical Data Exchange objective.

Response: The goal of the new Public Health Reporting Using TEFCA optional bonus measure is to encourage the use of networks participating in nationwide exchange under TEFCA without unfairly penalizing MIPS eligible clinicians who are not yet ready to participate and may need additional time and flexibility. We will continue to collaborate with other agencies including the CDC and ASTP/ONC to identify potential opportunities to expand TEFCA's supported public health use cases. MIPS eligible clinicians who are not ready to participate in health information exchange under TEFCA can still receive the five bonus points by reporting on either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure, or both. We will monitor performance on the new optional bonus measure and work with the CDC and ASTP/ONC to continue to monitor participation in TEFCA among PHAs, and determine if there is low rate of participation affecting the ability of MIPS eligible clinicians to report on this new Public Health Reporting Using TEFCA optional bonus measure and other bonus measures.

With regard to the comment pertaining to increasing the availability of bonus points for each optional bonus measure reported, we believe that providing available bonus points for each reported optional bonus measure would diminish the incentive to satisfactorily perform on the required measures. We believe that limiting optional bonus measures to a total maximum of five bonus points provides an appropriate balance between maintaining the primary importance of scoring well on required measures while also offering an incentive to participate in optional measures.

Comment: A few commenters recommended that CMS consider the readiness of PHAs for TEFCA participation and CMS resolve interoperability and data integrity issues with vendors and PHAs. Commenters recommended that CMS provide funding and technical assistance to small and rural practices, and community-based clinicians to encourage TEFCA participation. A commenter

recommended that CMS pursue federal investments in health IT infrastructures at state, local, tribal, and territorial PHAs. Another commenter requested that CMS consider the long development timeframe for implementation of new health IT functionality when proposing new requirements.

Response: We note that the Public Health Reporting Using TEFCA measure is an optional bonus measure with no technical integration requirements for MIPS eligible clinicians who determine that reporting on the optional bonus measure is infeasible. While we proposed that the functions of CEHRT must be used to exchange information with a PHA using TEFCA under the optional bonus measure, we did not identify specific standards or ONC health IT certification criteria that need to be adopted for this optional bonus measure. We recognize that the state of technology, available technical standards, and the technological readiness of MIPS eligible clinicians, including small and rural practices, may impact participation in TEFCA. We will continue to collaborate with other agencies to explore potential opportunities for technical support to promote participation and data exchange under TEFCA and strengthen public health reporting capabilities. We will continue to work with federal, state, local, tribal, and territorial partners to advance interoperability in public health reporting.

Comment: A few commenters recommended that CMS explicitly name the TEFCA Exchange Purpose Implementation Standard Operating Procedure, Level 2 in the measure text.

Response: In the TEFCA Exchange Purpose Implementation Standard Operating Procedure, Level 2 use cases refer to more specific data exchange contexts with accompanying exchange standards.[459] Although we recognize the value of focusing on more mature and standardized use cases, such as the Level 2 exchange use cases, the new Public Health Reporting Using TEFCA optional bonus measure aims to provide flexibility for MIPS eligible clinicians to engage in public health reporting under TEFCA across a variety of use cases. Limiting the measure to Level 2 use cases at this time could restrict participation and hinder measure adoption. However, we will monitor rates of participation and consider proposing refinements to the measure in future rulemaking based on feedback and real-world experience with TEFCA-supported exchanges.

Comment: A commenter recommended that CMS allow MIPS eligible clinicians to claim the

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[459] TEFCA Exchange Purpose (XP) Implementation SOP: Public Health, located at: https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-Public-Health-PH.pdf.

bonus under Active Engagement Option 1 (Pre-Production and Validation) rather than Active Engagement Option 2 (Validated Data Production). Another commenter encouraged CMS to continue allowing flexibility in how certified health IT capabilities are leveraged to meet the requirements of the measure.

Response: As the intent of the measure is to incentivize the electronic exchange of health information with PHAs, we believe performance is best reflected by validated data production under Active Engagement Option 2, in which MIPS eligible clinicians are actively exchanging production-level data with PHAs. Awarding the bonus only for production data transfer provides an appropriate balance, incentivizing meaningful use of such means of public health data exchange while still promoting flexibility in certified health IT capabilities necessary to accommodate diverse technical environments and resources. The new Public Health Reporting Using TEFCA optional bonus measure is designed to allow MIPS eligible clinicians to leverage various certified health IT capabilities to exchange data under TEFCA, ensuring they can choose the solutions that best fit their operational needs. We remain committed to supporting adaptable approaches that promote participation while minimizing burden, and we will continue to evaluate opportunities to enhance flexibility.

Comment: A few commenters recommended that TEFCA participation remain as an optional public health reporting method rather than becoming a requirement within the MIPS Promoting Interoperability performance category. A commenter recommended that CMS maintain all public health and registry reporting measures as attestation-based and voluntary. Another commenter expressed concern that TEFCA reporting may impose integration costs on specialty groups and requested that CMS consider a phase-in period before adding new requirements for measures involving public health reporting with TEFCA. Another commenter requested clarification as to whether or not MIPS eligible clinicians can attest to both the new Public Health Reporting Using TEFCA optional bonus measure and the Enabling Exchange Under TEFCA measure in the Health Information Exchange objective.

Response: We do not believe it is appropriate for all public health reporting measures in the MIPS Promoting Interoperability performance category to be voluntary; we consider public health reporting an important aspect of the meaningful use of CEHRT. The Public Health Reporting Using TEFCA measure is an optional bonus measure with no technical integration requirements for MIPS eligible clinicians who

determine that reporting on the bonus measure is infeasible. While the functions of CEHRT must be used, we have not identified specific standards or ONC health IT certification criteria that need to be adopted for this optional bonus measure; there should not be additional integration costs to meet the requirements of this optional bonus measure if both the MIPS eligible clinician and the applicable PHA are Participants/Sub-participants under TEFCA.

We note that MIPS eligible clinicians may attest to both the Public Health Reporting Using TEFCA optional bonus measure and the Enabling Exchange Under TEFCA measure in the Health Information Exchange objective provided that they meet the requirements for both measures.

After consideration of public comments, we are finalizing, as proposed, the proposal to adopt the Public Health Reporting Using TEFCA measure as an optional bonus measure under the Public Health and Clinical Data Exchange objective beginning with the CY 2026 performance period/2028 MIPS payment year. For the Public Health Reporting Using TEFCA optional bonus measure, a MIPS eligible clinician must: (1) Participate as a signatory to a Framework Agreement (as such term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on the ASTP/ONC website);[460] (2) Not be suspended from participating in TEFCA Exchange; (3) Submit health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) Be in active engagement Option 2 (Validated Data Production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) Use the functions of CEHRT to exchange with the PHA. Also, we note that in the FY 2026 IPPS/LTCH PPS final rule, we adopted this optional bonus measure under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (90 FR 37051 through 37056).

Also, we are finalizing, as proposed, the proposal to modify the regulation at § 414.1380(b)(4)(ii)(C) to clarify the scoring of optional bonus measures under the Public Health and Clinical Data Exchange objective beginning with the CY 2026 performance period/2028 MIPS payment year. A MIPS eligible clinician may earn a total of five bonus points if the MIPS eligible clinician attests

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[460] See Common Agreement for Nationwide Health Information Interoperability Version 2.1 November 2024 located at: *https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf.*

"Yes" to one, more than one, or all of the following optional bonus measures: the Public Health Reporting Using TEFCA measure, the Public Health Registry Reporting measure, the Clinical Data Registry Reporting measure, or the Syndromic Surveillance Reporting measure.

(f) Adoption of a Measure Suppression Policy for the MIPS Promoting Interoperability Performance Category Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year and for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) Beginning with the EHR Reporting Period in CY 2026

For MIPS, section 1848(q)(1)(A)(i) and (ii) of the Act provides, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards for a performance period and use such methodology to provide for a composite performance score (that is, MIPS final score) for each such clinician for each performance period. As discussed previously in the CY 2026 PFS proposed rule, section 1848(q)(2)(A)(iv) of the Act requires that we assess a MIPS eligible clinician's performance as a meaningful user of CEHRT to calculate the MIPS final score (90 FR 32725). Section 1848(q)(2)(B)(iv) of the Act provides that we apply the requirements established for a performance period under section 1848(o)(2) of the Act to determine whether a MIPS eligible clinician is a meaningful user of CEHRT.

For the Medicare Promoting Interoperability Program, sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act (as amended by the Health Information Technology for Economic and Clinical Health Act, Title XII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111-5) authorize downward payment adjustments under Medicare, beginning with FY 2015 for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for the applicable electronic health record (EHR) reporting period. Section 602 of Title VI, Division O of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) added section (d) hospitals in Puerto Rico as eligible hospitals under the Medicare EHR Incentive Program and extended the participation timeline for these hospitals such that downward payment adjustments were authorized beginning in FY 2022 for section (d) Puerto Rico hospitals that do not successfully demonstrate meaningful use of CEHRT for the applicable EHR reporting period.

For both the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, respectively, set forth three substantively similar criteria to determine whether a MIPS eligible clinician or an eligible hospital or CAH is a meaningful user of CEHRT. In addition, sections 1848(o)(2)(B)(i) and 1886(n)(3)(B)(i) of the Act, respectively, provide, in relevant part, that the Secretary shall select measures for purposes of the third criterion for assessing and determining if a MIPS eligible clinician, an eligible hospital, or a CAH is a meaningful user of CEHRT (sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act, respectively).

In the CY 2026 PFS proposed rule, we identified a need for additional flexibility in whether we use a measure to calculate scores or otherwise determine whether MIPS eligible clinicians meet the definition of a meaningful EHR user in the MIPS Promoting Interoperability performance category and eligible hospitals and CAHs meet the definition for the Medicare Promoting Interoperability Program (90 FR 32732 through 37234). This would account for the impact of changing conditions that are beyond the control of MIPS eligible clinicians, eligible hospitals, and CAHs, which arise outside of rulemaking for a given performance period or EHR reporting period. Such flexibility would allow us to ensure that MIPS eligible clinicians,[461] eligible hospitals, and CAHs are not impacted negatively by external factors as determined by CMS when they are being assessed for meeting measure requirements or meeting the definition of a meaningful user.

In the CY 2026 PFS proposed rule, we noted that a measure suppression policy would provide CMS with the flexibility to not score a measure for circumstances outside the control of MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category and eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (90 FR 32732). There may be circumstances that could impede the assessment of performance or a fair comparison of performance across applicable participants, creating the potential to unduly penalize a significant portion of MIPS eligible clinicians, eligible hospitals, and CAHs. We believe that there are certain circumstances that would warrant the necessity to suppress the scoring of a measure.

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[461] In the CY 2024 PFS final rule, the Medicare Shared Savings Program aligned its CEHRT use requirements for Accountable Care Organizations (ACOs) with the MIPS Promoting Interoperability performance category's requirements (88 FR 79124 through 79132). As codified at § 425.507, beginning with performance years on or after January 1, 2025, unless otherwise excluded, an ACO participant, ACO provider/supplier, and ACO professional that is a MIPS eligible clinician, Qualifying APM Participant (QP), or Partial Qualifying APM Participant (Partial QP) (each as defined at § 414.1305) must: (1) report the objectives and measures for MIPS Promoting Interoperability performance category; and (2) earn a performance category score for the MIPS Promoting Interoperability performance category.

On this basis, for both the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, beginning with the CY 2026 performance period/2028 MIPS payment year for MIPS eligible clinicians and the EHR reporting period in CY 2026 for eligible hospitals and CAHs, we proposed to adopt a measure suppression policy to permit CMS to exclude a measure from scoring or the determination of a meaningful EHR user for an applicable performance period/MIPS payment year or EHR reporting period in an applicable CY (90 FR 32733). Specifically, we proposed that such a measure suppression policy would allow CMS to exclude a measure from scoring due to circumstances that impede the effective measurement of a measure within the measure's applicable objective or to exclude such a measure from the determination of a meaningful EHR user for measures that are not scored. We have previously finalized similar measure suppression policies for the MIPS quality performance category (§ 414.1380(b)(1)(vii)(A)) and MIPS cost performance category (§ 414.1380(b)(2)(v)(A) and (B)). We modeled the proposed measure suppression policy based on the measure suppression policies previously finalized for the MIPS quality performance category and MIPS cost performance category at 90 FR 32732 through 37234 of the CY 2026 PFS proposed rule. We proposed the measure suppression policy for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program with some substantive differences, as compared to the similar measure suppression policies we previously finalized, to reflect more specific requirements of the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program.

For an applicable performance period/MIPS payment year or EHR reporting period, we proposed that CMS would determine whether certain circumstances exist warranting suppression of a measure within the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program based on CMS's consideration of one or more of the following factors:

- The nature, breadth, and duration of the circumstance's effect on MIPS eligible clinicians', eligible hospitals', and CAHs' ability to fulfill the measure requirement.
- The availability of certified health IT modules to fulfill the measure.
- The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

- Out-of-date or conflicting technical standards.
- Technical or operational capacity of required partners.
- Other factors as determined by CMS.

The aforementioned factors would provide a basis for CMS to determine when circumstances may warrant CMS to suppress the scoring of a measure, particularly when circumstances arise that may impact a significant portion or all MIPS eligible clinicians, eligible hospitals, and CAHs. We believe that there may be circumstances that affect the ability of MIPS eligible clinicians, eligible hospitals, and CAHs to meet the requirements of a measure that are outside of their control, such as technical or operational limitations experienced by required partners that limit the ability of MIPS eligible clinicians, eligible hospitals, and CAHs to complete specific elements of a measure. Also, there may be circumstances in which the timeline for the availability of certified health IT modules or updated technical standards may be delayed or incongruent with measure implementation requirements and, as a result, we believe that MIPS eligible clinicians, eligible hospitals, and CAHs should not be penalized or unfairly scored on a measure. If we transition to performance-based measures in the future, we may find that the data being reported may not be consistent due to various factors causing the data to not be valid or accurate.

Under the measure suppression policy, we proposed for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, our decision to suppress a measure would still require the measure to be reported. However, regardless of what data, attestation, or other information the MIPS eligible clinician, eligible hospital, or CAH reported for the measure, it would not affect the score for the applicable objective or the determination of a meaningful EHR user for measures that are not scored. For example, for a measure that requires a "Yes" or "No" response, the MIPS eligible clinician's, eligible hospital's, or CAH's score for the objective in which the measure is found would not be negatively impacted, regardless of whether it reported a "Yes" or a "No," as long as they reported a response.

In the CY 2026 PFS proposed rule, we noted that establishing a measure suppression policy would allow us to identify measures affected by one or more of the aforementioned factors outside of rulemaking to timely address such a situation (90 FR 32733). For any measure for which we determine it

must be suppressed based on one or more of the factors we have identified, we would notify MIPS eligible clinicians, eligible hospitals, and CAHs of the suppression via existing communication channels. The proposed policy would allow us to disseminate via a listserv announcement (MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program) and publish on a CMS website (MIPS Promoting Interoperability performance category) measures identified as being suppressed for an applicable CY performance period/MIPS payment year and EHR reporting period in an applicable CY, no later than the beginning of the applicable data submission period when technically feasible, which starts in January of the CY following the applicable performance period/EHR reporting period.

We proposed to adopt the measure suppression policy for the MIPS Promoting Interoperability performance category beginning with the CY 2026 performance period/2028 MIPS payment year and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs beginning with the EHR reporting period in CY 2026.

We proposed to codify the measure suppression policy at § 414.1380(b)(4)(iii) for the MIPS Promoting Interoperability performance category and § 495.24(f)(3) for the Medicare Promoting Interoperability Program. Specifically, we proposed to codify at § 414.1380(b)(4)(iii) that, beginning with the CY 2026 performance period/2028 MIPS payment year, if certain circumstances occur impacting CMS' assessment of performance of MIPS eligible clinicians on a measure specified for the MIPS Promoting Interoperability performance category at § 414.1375, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS' calculation of the MIPS Promoting Interoperability performance category objective score at § 414.1380(b)(4) or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. In addition, we proposed to codify at § 495.24(f)(3) that beginning with the EHR reporting period in CY 2026, if certain circumstances occur impacting CMS' assessment of performance of eligible hospitals and CAHs on a measure specified for the Medicare Promoting Interoperability Program, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS' calculation of the Medicare Promoting Interoperability Program objective score or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. Also, we proposed to codify at both §§ 414.1380(b)(4)(iii) and 495.24(f)(3) that CMS

would determine whether certain circumstances exist warranting suppression of a measure based on one or more of the following factors:

- The nature, breadth, and duration of the circumstance's effect on MIPS eligible clinicians', eligible hospitals', and CAHs' ability to fulfill the measure requirement.
- The availability of certified health IT modules to fulfill the measure.
- The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.
- Out-of-date or conflicting technical standards.
- Technical and operational capacity of required partners.
- Other factors as determined by CMS.

We solicited public comment on the proposal to adopt and codify a measure suppression policy for the MIPS Promoting Interoperability performance category beginning with the CY 2026 performance period/2028 MIPS payment year at § 414.1380(b)(4)(iii), and the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 at § 495.24(f)(3). The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to adopt a measure suppression policy. Some commenters stated that it would offer pragmatic program flexibility; some commenters cited the recent pause in Electronic Case Reporting onboarding among PHAs as an example of an issue warranting measure suppression due to circumstances outside a MIPS eligible clinician's, eligible hospital's, or CAH's control.

Response: We appreciate the support from commenters regarding the proposal to adopt a measure suppression policy. We agree that a measure suppression policy will provide pragmatic flexibility for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

Comment: A few commenters requested clarification regarding why the reporting of a suppressed measure would be required. The commenters requested that reporting of a suppressed measure be voluntary.

Response: The statutory authority for the MIPS Promoting Interoperability performance category

and the Medicare Promoting Interoperability Program, respectively, requires MIPS eligible clinicians, eligible hospitals, and CAHs to report on measures selected by the Secretary through rulemaking for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program. Consequently, as we developed the measure suppression policy for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, we did not intend or propose to remove or modify reporting requirements. We reiterate that in the event we determine it necessary to suppress a measure, measure suppression would not remove the measure from the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program nor change the requirement to report on the measure for the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program; thus, a suppressed measure is required to be reported for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

In regard to the technical and operational dynamics, the suppression of a measure for MIPS eligible clinicians, eligible hospitals, and CAHs for an applicable performance period/MIPS payment year or EHR reporting period is a feasible modification that can be made to the CMS systems (pertaining to the submission of data for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program) prior to the opening of an applicable submission period for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program while changes to measure requirements such as removing a measure or converting a measure to be optional would require more significant modifications to CMS systems that would not be able to completed prior to the opening of an applicable submission period. To prevent the delay of the opening of the submission period and disruption of the data submission process, we determined that it would be operationally feasible to update the CMS systems for the suppression of a measure given that such modification can be completed within a condensed timeframe of a few months. The measure suppression policy provides CMS with the flexibility to determine circumstances in which a measure would not be assessed for performance, enabling MIPS eligible clinicians, eligible hospitals, and CAHs to still meet the reporting requirements for the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program without having their scores negatively impacted due to circumstances

outside of their control.

In addition to the technical and operational impact to CMS systems, we believe that removing the reporting requirement for a suppressed measure may cause confusion among MIPS eligible clinicians, eligible hospitals, and CAHs as to their reporting responsibilities, as participants may be in different phases of measure implementation and reporting, particularly depending on the timeframe in which we identify a need to utilize the measure suppression policy for an applicable performance period/MIPS payment year or EHR reporting period. Also, we want to continue gathering available data on a measure even under conditions of measure suppression, which could assist in our understanding of the extent of the circumstance that led to suppression. For the aforementioned reasons, we believe that it is appropriate to continue requiring the reporting of a suppressed measure(s).

Comment: A few commenters requested that CMS provide additional information surrounding the criteria CMS will apply when determining whether to implement the measure suppression policy for a given year and how input from MIPS eligible clinicians, eligible hospitals, and CAHs is considered to inform CMS' decision to suppress a measure. A commenter encouraged CMS to provide specific, real-world examples of circumstances that would warrant suppression. Another commenter requested clarification regarding the duration of a suppressed measure. Separately, commenters requested that CMS provide advance notice and information about available exclusions to measures.

Response: For an applicable performance period/MIPS payment year or EHR reporting period, we will determine whether certain circumstances exist warranting suppression of a measure within the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program based on CMS' consideration of one or more of the following factors identified in the CY 2026 PFS proposed rule (90 FR 32733):

- The nature, breadth, and duration of the circumstance's effect on MIPS eligible clinicians', eligible hospitals', and CAHs' ability to fulfill the measure requirement.
- The availability of certified health IT modules to fulfill the measure.
- The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.
- Out-of-date or conflicting technical standards.

- Technical or operational capacity of required partners.
- Other factors as determined by CMS.

As we discussed in the CY 2026 PFS proposed rule, CMS would consider the aforementioned factors to determine when circumstances may warrant the suppression of a measure, particularly when circumstances arise that may impact a significant portion or all MIPS eligible clinicians, eligible hospitals, and CAHs (90 FR 32733).

We believe that there may be circumstances that affect the ability of MIPS eligible clinicians, eligible hospitals, and CAHs to meet the requirements of a measure that are outside of their control, such as technical or operational limitations experienced by required partners that limit the ability of MIPS eligible clinicians, eligible hospitals, and CAHs to complete specific elements of a measure. Also, there may be circumstances in which the timeline for the availability of certified health IT modules or updated technical standards may be delayed or incongruent with measure implementation requirements and, as a result, we believe that MIPS eligible clinicians, eligible hospitals, and CAHs should not be penalized or unfairly scored on a measure. If we transition to performance-based measures in the future, we may find that the data being reported may not be consistent due to various factors causing the data to not be valid or accurate.

We note that the duration of suppression for a measure would be for the entire CY of an applicable performance period or EHR reporting period. If prolonged issues persist regarding a given circumstance, CMS would assess the circumstance to determine if a measure would warrant suppression for a subsequent performance period/EHR reporting period.

We intend to rarely utilize the measure suppression policy, which will allow us to account for the impact of circumstances arising during a given performance period or EHR reporting period that are beyond the control of MIPS eligible clinicians, eligible hospitals, and CAHs. We recognize that there may be situations where MIPS eligible clinicians, eligible hospitals, CAHs; health IT vendors; or other interested parties may bring to our attention, or the attention of ASTP/ONC or the CDC regarding public health measures, circumstances these individuals or groups wish us to consider for the suppression of a measure, particularly if CMS is not aware of certain dynamics that could impact a substantial numbers of MIPS eligible clinicians, eligible hospitals, and CAHs. Also, it is possible that we may identify on our

own or with the collaboration of other governmental partners a situation that we determine requires measure suppression for a particular measure. Suppression of the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category for the CY 2025 performance period and the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025, as discussed in section XX of this final rule, is the most immediate example of a situation we have determined warrants the suppression of a measure. We recognize that there could be an array of other potential circumstances that could result in a measure to be suppressed. For example, if there were a months-long network outage in a large national Health Information Exchange or TEFCA QHIN, such case could result in MIPS eligible clinicians, eligible hospitals, and CAHs having to choose between claiming a hardship (if an available option for the MIPS eligible clinician, eligible hospital, or CAH) or failing to meet the requirements of the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program if their primary means of fulfilling the Health Information Exchange objective were unavailable. In such a case, we would also recognize that there are no applicable exclusions available under the Health Information Exchange objective for either program, and thus, we could consider measure suppression. Given that we cannot anticipate every scenario where measure suppression may be warranted, we specified that we would consider "other factors as determined by CMS" when deciding whether measure suppression is warranted for an applicable performance period/MIPS payment year or EHR reporting period.

Comment: A few commenters did not support the proposal given that there are existing measure exclusion criteria already providing a process to accommodate MIPS eligible clinicians, eligible hospitals, and CAHs presented with challenges outside their control.

Response: We note that not all measures within the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program include exclusions and, therefore, we do not believe that the availability of an exclusion for certain measures is sufficient to address circumstances outside the control of MIPS eligible clinicians, eligible hospitals, and CAHs that impact their ability to meet the requirements of all measures. Although we agree that measure exclusions often represent one avenue for MIPS eligible clinicians, eligible hospitals, and CAHs to avoid undue negative effects if they meet the requirements of the applicable exclusion, we believe that a measure suppression policy accounts

for an array of circumstances that may prevent MIPS eligible clinicians, eligible hospitals, and CAHs from meeting the requirements of a measure. We note that a measure exclusion pertains to a particular MIPS eligible clinician's, eligible hospital's, or CAH's circumstance; whereas, the measure suppression policy pertains to circumstances affecting a significant portion or all MIPS eligible clinicians, eligible hospitals, and CAHs.

Comment: Another commenter expressed concern that the measure suppression policy would prevent MIPS eligible clinicians, eligible hospitals, and CAHs from achieving full points in the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

Response: In the CY 2026 PFS proposed rule, we proposed to adopt a measure suppression policy that would suppress the scoring of a measure in order to avoid unfairly and negatively impacting a significant portion or all MIPS eligible clinicians, eligible hospitals, and CAHs due to factors outside of their control (90 FR 32732 through 32734). We noted that regardless of the data, attestation, or other information the MIPS eligible clinician, eligible hospital, or CAH reported for the measure, it would not affect the score for the applicable objective or the determination of a meaningful EHR user for measures that are not scored. Furthermore, we provided the following example, for a measure requiring a "Yes" or "No" response, a MIPS eligible clinician's, eligible hospital's, or CAH's score for the objective, in which the measure is found, would not be negatively impacted, regardless of whether a "Yes" or "No" was reported as long as the measure is reported (90 FR 32733).

We appreciate public comments bringing to our attention that in proposing to suppress the scoring of a measure, the effect of such action could be the antithesis of our goal of preventing an unfair and negative impact by unintentionally hindering the ability for a MIPS eligible clinician, eligible hospital, and CAH to achieve the maximum points available under the affected objective as well as the total score for the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program. The intention of the measure suppression policy is to prevent undue negative effects under the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program for MIPS eligible clinicians, eligible hospitals, and CAHs due to circumstances that are outside their control. As such, we believe that it would better reflect our intent, as well as serve the best interest of MIPS eligible clinicians, eligible hospitals, and CAHs, to score a suppressed measure

by allocating the maximum available points or providing full credit for an affected measure to ensure that MIPS eligible clinicians, eligible hospitals, and CAHs are not impacted negatively by external factors as determined by CMS when they are being assessed for meeting measure requirements or meeting the definition of a meaningful EHR user (90 FR 32732). Thus, we clarify in response to public comments and consistent with our intention for the measure suppression policy, that a suppressed measure will receive the maximum available points or full credit as long as the suppressed measure is reported. We note that a suppressed measure will not be assessed for performance, but MIPS eligible clinicians, eligible hospitals, and CAHs will be able to receive the maximum points available for a measure or full credit for a measure under an objective that contributes to the score of an objective.

For example, under the Electronic Prescribing objective, there are two measures (e-Prescribing measure and Query of Prescription Drug Monitoring Program (PDMP) measure) that have an allocation of 10 points each. If the e-Prescribing measure was suppressed, a MIPS eligible clinician, eligible hospital, or CAH would receive the maximum points available for the e-Prescribing measure. The e-Prescribing measure is a performance-based measure with a numerator and denominator. Given that the e-Prescribing measure is a performance-based measure, such measure is structured to receive a range of points dependent on performance. For performance-based measures that are suppressed, we would allocate the maximum available points for the measure as long as the suppressed measure is reported.

As another example, under the Public Health and Clinical Data Exchange objective, there is a cohort of two required measures for the MIPS Promoting Interoperability performance category (Immunization Registry Reporting measure and Electronic Case Reporting measure) and a cohort of six required measures for the Medicare Promoting Interoperability Program (Immunization Registry Reporting measure, Electronic Case Reporting measure, Syndromic Surveillance Reporting measure, Electronic Laboratory Reporting measure, Antimicrobial Use Surveillance measure; and Antimicrobial Resistance Surveillance measure). The measures under the Public Health and Clinical Data Exchange objective are attestation-based measures. The Public Health and Clinical Data Exchange objective has a total allocation of 25 points (each required measure does not have individual points attributed to it) and each required measure under such objective must meet the measure reporting requirements of the measure in order for a MIPS eligible clinician, eligible hospital, or CAH to meet the requirements of the Public

Health and Clinical Data Exchange objective. For a MIPS eligible clinician, eligible hospital, or CAH to receive the total allocation of 25 points for such objective, they must attest "Yes" or claim an exclusion for each of the required measures in order for such measures to be recognized as meeting the requirements for such objective and thus, receive credit for meeting the requirements of each required measure. If the Electronic Case Reporting measure within the Public Health and Clinical Data Exchange objective is suppressed, a MIPS eligible clinician, eligible hospital, or CAH would receive full credit for the Electronic Case Reporting measure as long as the attestation-based measure is reported (attest "Yes" or "No," or claim an applicable exclusion).

We note that if a suppressed measure is not reported, a MIPS eligible clinician, eligible hospital, and CAH would fail the measure requirement resulting in the MIPS eligible clinician, eligible hospital, and CAH receiving zero points for the suppressed measure or zero points for an objective in which the suppressed measure is one of a cohort of required measures to report due to not meeting the requirement to report the suppressed measure. Thus, we are modifying the proposed measure suppression policy accordingly.

Comment: A few commenters made recommendations regarding how the measure suppression policy could be applied to a measure, including circumstances impeding effective measurement. Specifically, a commenter recommended that CMS could require MIPS eligible clinicians, eligible hospitals, and CAHs to provide a rationale for their inability to meet a measure's requirements before CMS determines whether the measure should be suppressed. Another commenter encouraged CMS to publish a request for information (RFI) requesting feedback from healthcare organizations regarding which measures are burdensome or difficult to fulfill due to the measure suppression factors listed by CMS. Another commenter requested that announcements and sub-regulatory guidance regarding measure suppression be provided via multiple avenues to increase the likelihood that all affected parties receive prompt notification.

Response: We note that the factors we would consider in determining whether or not to suppress a measure would include circumstances affecting the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance. In regard to the comment requesting that CMS require MIPS eligible clinicians, eligible hospitals, and CAHs to

submit a rationale for not being able to meet the requirements of measure prior to a measure being suppressed, we note that the suppression of a measure applies to all MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category, and eligible clinicians and CAHs participating in the Medicare Promoting Interoperability Program. We would utilize the measure suppression policy when we are aware of a circumstance affecting all or a significant portion of MIPS eligible clinicians, eligible hospitals, or CAHs. As a result, it would be burdensome and unnecessary to require each MIPS eligible clinician, eligible hospital, or CAH to individually provide a rationale for their inability to meet a measure's requirements. Moreover, we do not intend for the measure suppression policy to be a means for individual MIPS eligible clinicians, eligible hospitals, and CAHs to request for a measure to be suppressed due to the MIPS eligible clinician's, eligible hospital's, or CAH's particular circumstances or inability to meet the requirements of a measure. We anticipate communicating with MIPS eligible clinicians, eligible hospitals, and CAHs in advance of the data submission period regarding the identification of a suppressed measure. Additionally, we anticipate that such rare circumstances in which we would utilize the measure suppression policy should require minimal to no additional action on the part MIPS eligible clinicians, eligible hospitals, and CAHs submitting data.

In regard to the comment requesting that CMS publish an RFI requesting feedback from healthcare organizations regarding which measures are burdensome or difficult to fulfill due to the measure suppression factors, we disagree that such RFIs are necessary or practical. Publishing RFIs each time CMS considers utilizing the measure suppression policy would likely be impractical, particularly due to changing conditions that may arise at any point during a given performance period or EHR reporting period, including outside of rulemaking. The measure suppression policy is intended to allow CMS to more timely address circumstances effecting MIPS eligible clinicians, eligible hospitals, and CAHs to meet the requirements of a measure due to external factors outside of their control. MIPS eligible clinicians, eligible hospitals, and CAHs are encouraged to contact CMS[462] [463] regarding any feedback or issues that they may be encountering as it pertains to the requirements of the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program. A

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[462] For the MIPS Promoting Interoperability performance category, contact the Quality Payment Program Service Center by sending an e-mail to QPP@cms.hhs.gov or creating a ticket at: *https://cmsqualitysupport.servicenowservices.com/ccsq_support_central*.
[463] For the Medicare Promoting Interoperability Program, send an e-mail to piprogramsupport@hsag.com or qnetsupport@cms.hhs.gov.

suppressed measure is required to be reported, but is not assessed for performance under the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

In the event that CMS decides to suppress a measure, we will notify MIPS eligible clinicians, eligible hospitals, and CAHs of the measure's suppression via existing communication channels, including the dissemination of a listserv announcement (MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program) and posting on a CMS website (MIPS Promoting Interoperability performance category) identifying suppressed measures for an applicable CY performance period/MIPS payment year and EHR reporting period in an applicable CY, no later than the beginning of the applicable data submission period when technically feasible, which starts in January of the CY following the applicable performance period/EHR reporting period.

After consideration of public comments, we are finalizing with modification the proposal to adopt a measure suppression policy that will not assess the performance of a suppressed measure and will allow MIPS eligible clinicians meeting the reporting requirements of the MIPS Promoting Interoperability performance category and eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program to receive the maximum available points for a measure or full credit for a measure that is part of a cohort of required measures to report under an objective as long as the identified suppressed measure is reported. The activation of the measure suppression policy does not change the data reporting requirements of the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program when a measure is identified as being suppressed for an applicable performance period/MIPS payment year and EHR reporting period. We recognize that some measures within the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program have specific points allocated to a measure, such as an attestation-based measure, or a range of points that could be earned for a measure, such as performance-based measures with a numerator and denominator structure; or specific points allocated to an objective in which a cohort of measures are required for reporting to meet the requirements of the objective. As such, we are modifying the measure suppression policy as proposed in § 414.1380(b)(4)(iii) for the MIPS Promoting Interoperability performance category and § 495.24(f)(3) for the Medicare Promoting Interoperability Program to reflect the following: A suppressed measure that is reported will receive the total number of

allocated points for an attestation-based measure, the maximum number of points that could be received for a performance-based measure, or full credit for a measure within an objective in which such measure is part of a cohort of required measures to report. We are adopting and codifying a measure suppression policy for the MIPS Promoting Interoperability performance category beginning with the CY 2026 performance period/2028 MIPS payment year at § 414.1380(b)(4)(iii), and the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 at § 495.24(f)(3).

Specifically, we are codifying at § 414.1380(b)(4)(iii) that, beginning with the CY 2026 performance period/2028 MIPS payment year, if certain circumstances occur that impact CMS' assessment of the performance of MIPS eligible clinicians on a measure selected for the MIPS Promoting Interoperability performance category at § 414.1375, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS' assessment of performance while allocating the maximum points available or providing full credit for the affected measure as long as the affected measure is reported, resulting in a suppressed measure contributing to the MIPS Promoting Interoperability performance category objective score at § 414.1380(b)(4); or excluding it from the determination of a meaningful EHR user if the affected measure is not scored.

In addition, we are codifying at § 495.24(f)(3) that, beginning with the EHR reporting period in CY 2026, if certain circumstances occur that impact CMS' assessment of the performance of eligible hospitals and CAHs on a measure selected for the Medicare Promoting Interoperability Program, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS' assessment of performance while allocating the maximum points available or providing full credit for the affected measure as long as the affected measure is reported, resulting in the suppressed measure contributing to the Medicare Promoting Interoperability Program objective score at § 495.24(f)(1)(i)(D); or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. Also, we are codifying at both §§ 414.1380(b)(4)(iii) and 495.24(f)(3) that CMS determines whether certain circumstances exist warranting suppression of a measure based on CMS' consideration of one or more of the following factors:

- The nature, breadth, and duration of the circumstance's effect on MIPS eligible clinicians', eligible hospitals', and CAHs' ability to fulfill the measure requirement.

- The availability of certified health IT modules to fulfill the measure.
- The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.
- Out-of-date or conflicting technical standards.
- Technical and operational capacity of required partners.
- Other factors as determined by CMS.

(g) Suppression of the Electronic Case Reporting Measure by Excluding the Measure from Scoring for the MIPS Promoting Interoperability Performance Category for the CY 2025 Performance Period/2027 MIPS Payment Year and the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2025

(i) Background: Public Health and Clinical Data Exchange Objective

The Public Health and Clinical Data Exchange objective of the MIPS Promoting Interoperability performance category for MIPS eligible clinicians and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs has been an important mechanism for encouraging healthcare data exchange for public health purposes. Effective responses to public health events require fast, accurate exchange of data between health care providers and Federal, State, and local public health agencies (PHAs). MIPS eligible clinicians, eligible hospitals, and CAHs collect these data for patient care, and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

For the MIPS Promoting Interoperability performance category, there have been two required measures and three optional bonus measures under the Public Health and Clinical Data Exchange objective through the CY 2025 performance period/2027 MIPS payment year: Immunization Registry Reporting (required); Electronic Case Reporting (required); Syndromic Surveillance Reporting (optional); Public Health Registry Reporting (optional); and Clinical Data Registry Reporting (optional). For background on this objective and its associated measures, we refer readers to the CY 2019 PFS final rule (83 FR 59815 through 59817). In the CY 2022 PFS final rule, we finalized the requirement for MIPS eligible clinicians to report 2 of the 5 measures associated with the Public Health and Clinical Data Exchange objective, beginning with the CY 2022 performance period/2024 MIPS payment year:

Immunization Registry Reporting and Electronic Case Reporting (86 FR 65469 through 65475). For background on this objective and its associated measures, we refer readers to the CY 2023 PFS final rule (87 FR 70071 through 70074). In section XX of this final rule, we are adopting a sixth measure as an optional bonus measure: Public Health Reporting Using TEFCA measure as an optional bonus measure under the Public Health and Clinical Data Exchange objective. Thus, beginning with the CY 2026 performance period/2028 MIPS payment year, there will be 2 required measures and four optional bonus measures under the Public Health and Clinical Data Exchange objective for the MIPS Promoting Interoperability performance category: Immunization Registry Reporting (required); Electronic Case Reporting (required); Syndromic Surveillance Reporting (optional); Public Health Registry Reporting (optional); Clinical Data Registry Reporting (optional); and Public Health Reporting Using TEFCA (optional).

For the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, there have been 8 measures under the Public Health and Clinical Data Exchange objective through the EHR reporting period in CY 2025: Immunization Registry Reporting (required); Electronic Case Reporting (required); Syndromic Surveillance Reporting (required); Electronic Laboratory Reporting (required); Antimicrobial Use Surveillance (required); Antimicrobial Resistance Surveillance (required); Public Health Registry Reporting (optional); and Clinical Data Registry Reporting (optional). In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37056), we adopted a ninth measure as an optional bonus measure: Public Health Reporting Using TEFCA. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45478), we finalized the requirement for eligible hospitals and CAHs to report four measures associated with the Public Health and Clinical Data Exchange objective, beginning with the EHR reporting period in CY 2022: Immunization Registry Reporting; Electronic Case Reporting; Syndromic Surveillance Reporting; Electronic Laboratory Reporting. We subsequently finalized the requirement for eligible hospitals and CAHs to also report Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance in the FY 2024 IPPS/LTCH PPS final rule (87 FR 49335 through 49337). Thus, beginning with the EHR reporting period in CY 2026, there will be 6 required measures and 3 optional bonus measures under the Public Health and Clinical Data Exchange objective for the Medicare Promoting Interoperability Program: Immunization Registry Reporting (required); Electronic Case Reporting

(required); Syndromic Surveillance Reporting (required); Electronic Laboratory Reporting (required); Antimicrobial Use Surveillance (required); Antimicrobial Resistance Surveillance (required); Public Health Registry Reporting (optional); Clinical Data Registry Reporting (optional); and Public Health Reporting Using TEFCA (optional).

The Public Health and Clinical Data Exchange objective of the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program has been an important mechanism for encouraging data exchange between MIPS eligible clinicians, eligible hospitals, CAHs, and PHAs. Requiring MIPS eligible clinicians, eligible hospitals, and CAHs to report on required measures provides an ongoing incentive for EHR vendors to implement the necessary capabilities in their products and encourages MIPS eligible clinicians, eligible hospitals, and CAHs to engage in the reporting activities described in the measures.

As noted previously, MIPS eligible clinicians, eligible hospitals, and CAHs are required to report the Electronic Case Reporting measure for the Public Health and Clinical Data Exchange objective as specified for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, respectively. The Electronic Case Reporting measure currently requires that the MIPS eligible clinician, eligible hospital, or CAH be in active engagement with a PHA to submit electronic case reporting of reportable conditions. A MIPS eligible clinician, eligible hospital, or CAH is required to report their level of active engagement as either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production).

As described in the CY 2023 PFS final rule (87 FR 70072) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49338), we currently define "active engagement" as when the MIPS eligible clinician, eligible hospital, or CAH is in the process of moving towards sending "production data" to a PHA or clinical data registry (CDR), or is sending production data to a PHA or CDR. We further noted that the term "production data" refers to data generated through clinical processes involving patient care; the term is used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers (87 FR 70072; 87 FR 49337 through 49340).

In the CY 2023 PFS final rule (70071 through 70074) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337 through 49340), we finalized that, beginning with the CY 2023 performance

period/2025 MIPS payment year and the EHR reporting period in CY 2023, respectively, a MIPS eligible clinician, eligible hospital, or CAH must indicate its level of active engagement at either Option 1 (Pre-production and Validation) or Option 2 (Validated Data Production) to fulfill the Electronic Case Reporting measure and other measures specified for the Public Health and Clinical Data Exchange objective. We further finalized that generally, beginning with the CY 2024 performance period/2026 MIPS payment system and the EHR reporting period in CY 2024, MIPS eligible clinicians, eligible hospitals, and CAHs may spend only one performance period at the Option 1 (Pre-production and Validation) level of active engagement for the Electronic Case Reporting measure and other measures specified for the Public Health and Clinical Data Exchange objective, and MIPS eligible clinicians, eligible hospitals and CAHs must progress to the Option 2 (Validated Data Production) level of active engagement in the next EHR reporting period for which they report the measure (87 FR 70071 through 70074; 87 FR 49340 through 49342). The only exception to this requirement that we finalized is that, in the event a MIPS eligible clinician, eligible hospital, or CAH chooses to switch between one or more PHAs or CDRs, they will be permitted to spend on additional performance period at Option 1 (Pre-production and Validation) to assist with onboarding to the new CDR or PHA (87 FR 70071 through 70074; 87 FR 49340 through 49342).

Additional information on the history of the Electronic Case Reporting measure can be found in prior rulemakings for the predecessor Medicare EHR Incentive Programs for Eligible Professionals and for Eligible Hospitals and Critical Access Hospitals,[464] the MIPS Promoting Interoperability performance category,[465] and the Medicare Promoting Interoperability Program.[466]

For both the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program, the Electronic Case Reporting measure also includes three exclusions. A MIPS eligible clinician, eligible hospital, or CAH meeting one or more of the three established criteria may claim an exclusion from performing and reporting the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program,

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[464] We refer readers to Stage 1 final rule (75 FR 1844), Stage 2 final rule (77 FR 13698), and Stage 3 final rule (80 FR 62762),

[465] We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77008), CY 2018 Quality Payment Program final rule (82 FR 53568), the CY 2019 PFS final rule (83 FR 59815), the CY 2022 PFS final rule (86 FR 65469 through 65475), and the CY 2023 PFS final rule (87 FR 70071 through 70082).

[466] We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45478).

respectively. The first exclusion criterion specifies that the MIPS eligible clinician, eligible hospital, or CAH does not treat or diagnose any reportable diseases for which data are collected by its jurisdiction's reportable disease system during the performance period or EHR reporting period (Exclusion 1). The second exclusion criterion specifies that the MIPS eligible clinician, eligible hospital, or CAH operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period (Exclusion 2). The third exclusion criterion specifies that the MIPS eligible clinician, eligible hospital, or CAH operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of six months prior to the start of the performance period (Exclusion 3). We interpret "capable of receiving electronic case reporting data in the specific standards required" in Exclusion 2 to mean that there is not a PHA in a MIPS eligible clinician's, eligible hospital's, or CAH's jurisdiction that has the ability to advance, and has advanced, a MIPS eligible clinician, eligible hospital, or CAH registered with the PHA to Active Engagement Option 2: Validated Data Production in the timeframe required for the MIPS eligible clinician, eligible hospital, or CAH to achieve Validated Data Production under the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program. For information regarding the 2025 measure specifications for the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, we refer readers to: *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2025-MIPS-Promoting-Interoperability-Measure-Electronic-Case-Reporting-Updated-April-2025.pdf* and *https://www.cms.gov/files/document/cms-specifications-manual-ehr-period-cy-2025.pdf*.

(ii) Suppression of the Electronic Case Reporting Measure for the CY 2025 Performance Period and the EHR Reporting Period in CY 2025

As discussed in the CY 2026 PFS proposed rule (90 FR 32735), MIPS eligible clinicians, eligible hospitals, and CAHs have been required to register with a PHA and send testing files (Pre-production and Data Validation files) to report the Electronic Case Reporting measure at the Option 1 level of active engagement (87 FR 70071 through 70074; 87 FR 49338 through 87 FR 49342). Beginning with the CY 2024 performance period/2026 MIPS payment system and the EHR reporting period in CY 2024, MIPS

eligible clinicians, eligible hospitals, and CAHs may spend only one performance period at the Option 1 (Pre-production and Validation) level of active engagement for the Electronic Case Reporting measure, and they must progress to the Option 2 (Validated Data Production) level of active engagement in the next performance period or EHR reporting period for which they report the measure (87 FR 70071 through 70074; 87 FR 49338 through 87 FR 49342). Therefore, beginning with the CY 2025 performance period and EHR reporting period in CY 2025, many MIPS eligible clinicians, eligible hospitals, and CAHs may need to submit case files (that is, production data) using CEHRT to their PHA to report that they have progressed to the Option 2 level of active engagement for the Electronic Case Reporting measure.

In regard to the level of engagement pertaining to Option 1 and Option 2 for the CY 2025 performance period and EHR reporting period in CY 2025, we noted in the CY 2026 PFS proposed rule that the CDC temporarily paused its electronic case reporting registration and onboarding of new health care organizations (HCOs) in order to establish a more efficient and automated process (90 FR 32735 and 32736). During such time, the CDC has been evaluating the onboarding process for HCOs and their EHR vendors to establish a more sustainable long-term path for broadscale adoption and integration of healthcare and electronic case reporting data. On June 6, 2025, we shared this information through the Quality Payment Program (QPP) and Medicare Promoting Interoperability Program listserv announcements and published this information on the QPP Resource Library webpage (located at: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3268/2025-MIPS-Promoting-Interoperability-CDC-Pause-In-eCR-Onboarding.pdf*) and CMS QualityNet Hospital Inpatient Notifications webpage (located at: https://qualitynet.cms.gov/files/68437ab1416b533f04e5f5f0?filename=2025-59-IP.pdf). Due to this temporary pause, some MIPS eligible clinicians, eligible hospitals, and CAHs may not meet the electronic case reporting registration and onboarding requirements by the end of the CY 2025 performance period and EHR reporting period in CY 2025. The onboarding process includes a timeframe that accounts for connecting to intermediaries to send electronic case reporting data to PHAs with HCOs and EHR vendors. This temporary pause is enabling the CDC to evaluate the onboarding process for HCOs and their EHR vendors. The CDC is enhancing its electronic case reporting modernization

initiatives and creating a sustainable long-term strategy for the widespread adoption and integration of healthcare and electronic case reporting data.

To avoid undue adverse consequences for MIPS eligible clinicians, eligible hospitals, and CAHs as a result of such circumstances, which are outside of their control, we proposed to suppress the Electronic Case Reporting measure (90 FR 32735 and 32736). Specifically, we proposed to exclude the Electronic Case Reporting measure from scoring under the MIPS Promoting Interoperability performance category for the CY 2025 performance period and the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025.

We proposed that we would suppress the Electronic Case Reporting measure by excluding it from calculations for scoring purposes, but MIPS eligible clinicians, eligible hospitals, and CAHs would continue to be required to report the measure, in which they would either attest "Yes" or "No" to meeting the requirements pertaining to Option 1 and Option 2, or claim an applicable exclusion. We noted that as long as MIPS eligible clinicians, eligible hospitals, and CAHs report responses, their score for the Public Health and Clinical Data Exchange objective of the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program, as applicable, would not be adversely affected irrespective of the responses reported for this measure.

We proposed to suppress the Electronic Case Reporting measure through rulemaking in order to notify MIPS eligible clinicians, eligible hospitals, and CAHs of how we intend to address the issues related to CDC's pause on onboarding, which may affect MIPS eligible clinicians', eligible hospitals', and CAHs' ability to meet requirements of the Electronic Case Reporting measure for the MIPS Promoting Interoperability performance category for the CY 2025 performance period and the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025. In the absence of a measure suppression policy currently for the CY 2025 performance period and the EHR reporting period in CY 2025, we noted that we would utilize the CY 2026 PFS proposed rule to seek public comment regarding the proposal to suppress the Electronic Case Reporting measure due to the CDC's pause on onboarding and subsequently, and this final rule to communicate the official suppression status of the Electronic Case Reporting measure and address the scoring of the Electronic Case Reporting measure.

In the CY 2026 PFS proposed rule, we noted that the Public Health and Clinical Data Exchange objective requirements and the 25 points attributed to the objective under the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program would remain the same (90 FR 32736). The Electronic Case Reporting measure would continue to be a required measure even though we proposed to suppress it by excluding it from our scoring calculations. The 25 points attributed to the Public Health and Clinical Data Exchange objective under the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program would apply to the measure(s) in the objective that are required and not suppressed. Moreover, we noted that the proposal does not affect the measure specifications nor the required reporting of the measure, but merely affects whether the measure is scored for purposes of the applicable objective.

We solicited public comment on the proposal to suppress the Electronic Case Reporting measure by excluding the measure from scoring for MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category, and eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program for the CY 2025 performance period and the EHR reporting period in CY 2025.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to suppress the scoring of the Electronic Case Reporting measure for the CY 2025 performance period/EHR reporting period in CY 2025, citing the pause in PHA onboarding of new health care organizations for reporting these data.

Response: We appreciate the support from commenters regarding the proposal to suppress the Electronic Case Reporting measure for the CY 2025 performance period/EHR reporting period in CY 2025.

Comment: A few commenters noted that vendor and PHA onboarding issues could persist beyond CY 2026, preventing MIPS eligible clinicians, eligible hospitals, and CAHs from advancing to Option 2 of active engagement in a timely manner and requested that CMS suppress the requirement that MIPS eligible clinicians, eligible hospitals, and CAHs may only spend one performance period in Option 1 (Pre-Production and Validation) before progressing to Option 2 (Validated Data Production). A few commenters recommended that CMS extend the suppression of the Electronic Case Reporting measure

through the CY 2026 performance period/EHR reporting period in CY 2026 to align with the enforcement discretion recently issued by ASTP/ONC regarding the electronic case reporting certification updates.

Response: During the CY 2026 performance period/EHR reporting period in CY 2026, we will continue to work with the CDC to assess whether the Electronic Case Reporting measure warrants suppression for the CY 2026 performance period/EHR reporting period in CY 2026. However, at this juncture, we decline to suppress the Electronic Case Reporting measure beyond the CY 2025 performance period and the EHR reporting period in CY 2025 without more specific information regarding the extent of the effect, if any, the existing circumstance will have on the CY 2026 performance period/EHR reporting period in CY 2026.

In regard to the comment requesting that CMS suspend its requirement to only allow MIPS eligible clinicians, eligible hospitals, and CAHs to spend one performance period in Option 1 (Pre-Production and Validation) before progressing to Option 2 (Validated Data Production), we do not believe that a change to the requirement is necessary given that a significant portion of MIPS eligible clinicians, eligible hospitals, and CAHs attested "Yes" to Option 1 for the CY 2024 performance period/EHR reporting period in CY 2024 and the Electronic Case Reporting measure is suppressed for the CY 2025 performance period/EHR reporting period in CY 2025, which provides additional time for MIPS eligible clinicians, eligible hospitals, and CAHs to progress from Option 1 (Pre-Production and Validation) to Option 2 (Validated Data Production).

On July 31, 2025, ASTP/ONC issued a notice of enforcement discretion regarding the electronic case reporting certification criteria under the ONC Health IT Certification Program.[467] We note that the enforcement discretion takes effect immediately and will remain in place until December 31, 2026, or until the U.S. Department of Health and Human Services completes a deregulatory action revising the electronic case reporting certification criterion, whichever comes first. The enforcement discretion announces that ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from certified health IT not complying with the adopted standards finalized in 45 CFR 170.315(f)(5) so long as the health IT remains conformant with

[467] Office of the National Coordinator for Health IT, Electronic Case Reporting Certification Criterion Enforcement Discretion Notice located at: https://www.healthit.gov/topic/electronic-case-reporting-certification-criterion-enforcement-discretion-notice.

either 45 CFR 170.315(f)(5)(i) or the requirements in (f)(5)(ii). The enforcement discretion notices also states that ASTP/ONC will not take any enforcement action under 45 CFR 170.565 against an ONC-ACB based on non-compliance with 45 CFR 170.550 for certifying a Health IT Module that is presented for certification to the "transmission to public health agencies – electronic case reporting" certification criterion (45 CFR 170.315(f)(5)), where the Health IT Module demonstrates and maintains conformance with paragraph (f)(5)(i) or certain functional requirements of paragraph (f)(5)(ii). The enforcement discretion announced by ASTP/ONC would reduce certification criteria compliance requirements and provides developers flexibility to align with the evolving HL7 standards. Developers are encouraged to continue preparing for broader adoption of modern electronic case reporting standards. This enforcement discretion permits developers to focus on meeting the functional capabilities of the certification criterion rather than specific technical standards. At this juncture, we do not believe that the enforcement discretion that reduces the certification compliance burden for health IT developers warrants suppressing the Electronic Case Reporting measure for the CY 2026 performance period/EHR reporting period in CY 2026 for MIPS eligible clinicians, eligible hospitals, and CAHs given that enforcement discretion does not change the functionality of electronic case reporting.

Comment: A few commenters did not support the proposal to suppress the Electronic Case Reporting measure because they believe that the MIPS eligible clinicians, eligible hospitals, and CAHs that can successfully report on the measure will be detrimentally impacted by a blanket suppression policy by being unable to receive credit for their work. A few commenters did not support the proposal because they believed it would remove the incentive to perform electronic case reporting. A commenter recommended that CMS only provide an exclusion from reporting to any MIPS eligible clinician, eligible hospital, or CAH that was unable to register for electronic case reporting during the CY 2025 performance period/EHR reporting period in CY 2025. A few commenters recommended that, rather than suppression, MIPS eligible clinicians, eligible hospitals, and CAHs claim an exclusion following existing policies, while a commenter recommended that CMS consider introducing a fourth exclusion option that MIPS eligible clinicians, eligible hospitals, and CAHs could claim if they provide documentation of attempted onboarding, but could not complete onboarding during the CY 2025 performance period/EHR reporting period in CY 2025. Another commenter suggested that CMS consider

offering bonus points to MIPS eligible clinicians, eligible hospitals, and CAHs that can attest to meeting the requirements of the Electronic Case Reporting measure rather than suppress the scoring of the Electronic Case Reporting measure. A commenter recommended that CMS suppress the Electronic Case Reporting measure for only MIPS eligible clinicians, eligible hospitals, and CAHs that are not able to meet the requirements of the measure and redistribute the points to another objective. Another commenter recommended the removal of the points value from the Electronic Case Reporting measure entirely rather than redistributing the points to another objective and inflating the weight of another measure or objective.

Response: In this final rule, we are finalizing with modification the proposal to suppress the Electronic Case Reporting measure for the CY 2025 performance period/EHR reporting period in CY 2025. Based on public comments, we acknowledge that the proposal to suppress the Electronic Case Reporting measure by excluding the measure from scoring could potentially impede and hinder a MIPS eligible clinician's, eligible hospital's, or CAH's ability to achieve that maximum points available under the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program. We did not intend for the proposal to have such a potential consequence. The proposal to suppress the Electronic Case Reporting measure was merely intended to prevent negative implications for MIPS eligible clinicians, eligible hospitals, and CAHs that are not able to meet the measure requirements resulting from circumstances outside of their control, specifically arising from CDC's temporary pause in its electronic case reporting registration and onboarding of new HCOs (90 FR 32735 and 32736).

Thus, we believe that it would be in the best interest of MIPS eligible clinicians, eligible hospitals, and CAHs to receive full credit for reporting the suppressed Electronic Care Reporting measure, which is a measure that is part of a cohort of required measures to report under the Public Health and Clinical Data Exchange objective. While the suppressed Electronic Case Reporting measure will not be assessed for performance, MIPS eligible clinicians, eligible hospitals, and CAHs reporting the suppressed Electronic Case Reporting measure will receive full credit as long as they report the measure. If the suppressed Electronic Case Reporting measure is not reported, a MIPS eligible clinician, eligible hospital, and CAH would fail the reporting requirements under the Public Health and Clinical Data Exchange objective (receive zero points). We believe that such an approach would not cause confusion or

create complexities in understanding the implementation of measure suppression.

We believe the most appropriate approach to ensure that MIPS eligible clinicians, eligible hospitals, and CAHs do not experience an increase in burden or negative effects resulting from circumstances outside of their control is to allow MIPS eligible clinicians, eligible hospitals, and CAHs reporting the suppressed Electronic Case Reporting measure to receive full credit. Also, we believe that such an approach is operationally feasible to implement prior to the opening of the submission period for reporting data pertaining to the requirements for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program without delaying the opening of the submission period and disrupting the reporting of non-suppressed measures. Thus, we disagree with commenters recommending alternative options such as the following: CMS establishing an exclusion from reporting the Electronic Case Reporting measure if a MIPS eligible clinician, eligible hospital, CAH was unable to register for electronic case reporting during the CY 2025 performance period/EHR reporting period in CY 2025 and CMS requesting that an affected MIPS eligible clinician, eligible hospital, and CAH submit supporting documentation; CMS providing bonus points to MIPS eligible clinicians, eligible hospitals, and CAHs that are able to meet the measure requirements; CMS suppressing the Electronic Case Reporting measure for only MIPS eligible clinicians, eligible hospitals, and CAHs that are not able to meet the requirements of the measure and redistribute the points to another objective; and CMS removing the points value of the Electronic Case Reporting measure entirely rather than redistributing the points to another objective and inflating the weight of another measure or objective. Such alternative options as recommended by commenters would not be technically and operationally feasible to implement prior to the opening of the submission period.

To report the suppressed Electronic Case Reporting measure, MIPS eligible clinicians, eligible hospitals, and CAHs will either attest “Yes” or “No” to meeting the requirements pertaining to Option 1 and Option 2, or claim an applicable exclusion. As long as MIPS eligible clinicians, eligible hospitals, and CAHs report responses, they will receive full credit for reporting the suppressed Electronic Case Reporting measure, which will contribute to meeting the cohort of required measures under the Public Health and Clinical Data Exchange objective of the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program, as applicable. We note that a MIPS

eligible clinician's, eligible hospital's, and CAH's score for the Public Health and Clinical Data Exchange objective would not be adversely affected irrespective of the responses reported for such measure. We note that if an applicable exclusion is claimed, the suppressed Electronic Case Reporting measure will receive full credit, which will contribute to meeting the cohort of required measures under the Public Health and Clinical Data Exchange objective.

The Electronic Case Reporting measure is included in the Public Health and Clinical Data Exchange objective. The Public Health and Clinical Data Exchange objective includes a cohort of two required measures for the MIPS Promoting Interoperability performance category and a cohort of six required measures for the Medicare Promoting Interoperability Program. In the event that a MIPS eligible clinician, eligible hospital, or CAH claims an exclusion for the suppressed Electronic Case Reporting measure and claims exclusions for the other required measures within the Public Health and Clinical Data Exchange objective, they will receive full credit for reporting the suppressed Electronic Case Reporting measure and consequently, will receive the total available points (25) for the Public Health and Clinical Data Exchange objective. In the absence of any measure suppression, if an exclusion is claimed for each required measure under the Public Health and Clinical Data Exchange objective, the total points allocated to such objective would be redistributed to another objective. Such redistribution will not occur when the Electronic Case Reporting measure is suppressed and all other required measure(s) under such objective have an exclusion claimed because in the case of reporting the suppressed Electronic Case Reporting measure, such measure will receive full credit even when an exclusion is claimed, which will contribute to meeting the cohort of required measures under the Public Health and Clinical Data Exchange objective.

Comment: A few commenters requested clarification regarding the relationship between measure suppression and the currently available measure exclusions and the hardship policy.

Response: As discussed in more detail in section XX of this final rule regarding the adoption of a measure suppression policy, we note that the suppression of the Electronic Case Reporting measure merely excludes a measure from being assessed for performance. The suppressed Electronic Case Reporting measure is required to be reported, which means MIPS eligible clinicians, eligible hospitals, and CAHs will either attest "Yes" or "No" to meeting the requirements pertaining to Option 1 and Option

2 or claim an applicable exclusion. As long as MIPS eligible clinicians, eligible hospitals, and CAHs report responses, they will receive full credit for reporting the suppressed Electronic Case Reporting measure, which will contribute to meeting the cohort of required measures under the Public Health and Clinical Data Exchange objective. We note that a MIPS eligible clinician's, eligible hospital's, and CAH's score for the Public Health and Clinical Data Exchange objective of the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program, as applicable, would not be adversely affected irrespective of the responses reported for such measure. The hardship exception policy remains in place as an option for MIPS eligible clinicians, eligible hospitals, and CAHs with individual specified circumstances that prevent reporting of other required measures, but it would not be necessary to apply for a hardship exception if the sole circumstance for applying is related to the suppressed measure because measure suppression would already prevent negative effects from attesting "No" to the measure. While three exclusions are available for the Electronic Case Reporting measure and MIPS eligible clinicians, eligible hospitals, and CAHs may submit an applicable exclusion as their response to the measure if applicable, such available exclusions may not address every situation where a MIPS eligible clinician, eligible hospital, and CAH has been negatively impacted by the CDC's onboarding pause during the CY 2025 performance period/EHR reporting period in CY 2025.

Comment: A few commenters encouraged CMS and CDC to provide clear communication and give timely updates about the resumption of electronic case reporting onboarding. A commenter requested that CMS encourage CDC to reopen registration and onboarding for electronic case reporting and cautioned that measure suppression would have an impact on the ability of PHAs to monitor disease trends and efficiently manage outbreaks.

Response: We will share the public comments received with the CDC given that the CDC is responsible for the resumption of electronic case reporting onboarding. We note that all States and the District of Columbia continue to have statutory or regulatory requirements for case reporting and they allow several reporting methods even if an automated electronic method is not yet available.[468]

Comment: A few commenters recommended that CMS not require MIPS eligible clinicians, eligible hospitals, and CAHs to report on a suppressed measure.

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[468] https://www.pew.org/en/research-and-analysis/reports/2024/12/state-public-health-data-reporting-policies-and-practices-vary-widely.

Response: We disagree with commenters regarding the recommendation for MIPS eligible clinicians, eligible hospitals, and CAHs to not be required to report on a suppressed measure. As discussed in the CY 2026 PFS proposed rule (90 FR 32733) and section XX of this final rule regarding the adoption of a measure suppression policy, we note that we do not have any intention of removing or modifying reporting requirements. We reiterate that in the event a measure suppression becomes necessary, as with the Electronic Case Reporting measure for the CY 2025 performance period/EHR reporting period in CY 2025, suppression would not remove the measure from the MIPS Promoting Interoperability performance category or the Medicare Promoting Interoperability Program, nor change the requirement to report on the measure for the respective program. In regard to the technical and operational dynamics, it is not operationally feasible to modify CMS systems to remove the Electronic Case Reporting measure prior to the opening of the submission period without risking delay in the opening of the submission period for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program or disrupting the reporting of non-suppressed measures. However, we have determined that it is operationally feasible to update the CMS systems prior to the opening of the submission period. In addition to the technical and operational impact to CMS systems, we believe that removing the reporting requirement for a suppressed measure may cause confusion among eligible clinicians, hospitals, and CAHs as to their reporting responsibilities, as participants may be in different phases of measure implementation and reporting. Also, we want to continue gathering available data on the Electronic Case Reporting measure to help us better understand the impacts of the circumstance that led to suppression. For the aforementioned reasons, we believe that it is appropriate to continue requiring the reporting of the suppressed Electronic Case Reporting measure.

Comment: A few commenters requested that CMS clarify its expectations regarding the level of active engagement for the CY 2026 performance period/EHR reporting period in CY 2026 in terms of the expectations for MIPS eligible clinicians, eligible hospitals, and CAHs impacted by onboarding difficulties during the CY 2025 performance period/EHR reporting period in CY 2025. A commenter requested clarification regarding how to manage active engagement attestations subsequent to EHR transitions. Commenters gave the example of a MIPS eligible clinician who is in active engagement Option 2, but replacing the EHR forces the MIPS eligible clinician to re-establish a new public health

reporting interface. Commenters requested guidance regarding which active engagement option would be most appropriate for attestation in that circumstance.

Response: Regarding the required level of active engagement, there is no change to the previously finalized policy (87 FR 70074) that MIPS eligible clinicians, eligible hospitals, and CAHs may only spend one MIPS performance period/EHR reporting period in Option 1 (Pre-Production and Validation) before progressing to Option 2 (Validated Data Production). Therefore, if a MIPS eligible clinician, eligible hospital, or CAH attested to spending a prior MIPS performance period/EHR reporting period in Option 1, they would be required to progress to Option 2 in the next MIPS performance period/EHR reporting period in which the suppressed measure is no longer suppressed. Similarly, if an EHR replacement forces a MIPS eligible clinician, eligible hospital, or CAH to re-establish a new public health reporting interface and re-register with their PHA, current policy requires them to attest to Option 2 (Validated Data Production) that year if they have already spent one EHR reporting period or performance period in Option 1 (Pre-Production and Validation) (87 FR 70074).

After consideration of public comments, we are finalizing with modification the proposal to suppress the Electronic Case Reporting measure. In suppressing the Electronic Case Reporting measure, we will not assess the Electronic Case Reporting measure for performance for MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category for the CY 2025 performance period, and eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025. While the Electronic Case Reporting measure is identified as being suppressed for the purposes of assessing performance, the measure continues to be a required measure for reporting data under the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program. MIPS eligible clinicians, eligible hospitals, and CAHs reporting the suppressed Electronic Case Reporting measure (attest "Yes" or "No" to meeting the requirements pertaining to Option 1 and Option 2, or claim an applicable exclusion) will be able to receive full credit for the measure under the Public Health and Clinical Data Exchange objective. A MIPS eligible clinician's, eligible hospital's, and CAH's score for the Public Health and Clinical Data Exchange objective would not be adversely affected irrespective of the responses reported for the suppressed Electronic Case Reporting measure. If the suppressed Electronic Case Reporting

measure is not reported, a MIPS eligible clinician, eligible hospital, and CAH would fail to meet the requirements under the Public Health and Clinical Data Exchange objective (receive zero points). In the event that a MIPS eligible clinician, eligible hospital, or CAH claims an exclusion for the suppressed Electronic Case Reporting measure and claims exclusions for the other required measures within the Public Health and Clinical Data Exchange objective, the available points for the Public Health and Clinical Data Exchange objective would not be redistributed to another objective (point redistribution for cases when an exclusion is claimed for all of the measures within the Public Health and Clinical Data Exchange objective) because in the case of reporting the suppressed Electronic Case Reporting measure, such measure will receive full credit resulting in meeting the requirements of the Public Health and Clinical Data Exchange objective and thus, will receive the maximum available points within the objective even when an exclusion is claimed.

(h) Requirements for the MIPS Promoting Interoperability Performance Category for the CY 2026 Performance Period/2028 MIPS Payment Year

(i) Objectives and Measures for the CY 2026 Performance Period/2028 MIPS Payment Year

For reference, Table C-G2 sets forth the objectives and measures for the MIPS Promoting Interoperability performance category that would be required for the CY 2026 performance period/2028 MIPS payment year. Table C-G2 reflects finalized modifications to previously established objectives and measures, including the establishment a new optional bonus measure, under the MIPS Promoting Interoperability performance category.

TABLE C-G2: OBJECTIVES AND MEASURES FOR THE MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of Prescription Drug Monitoring Program (PDMP): For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other healthcare providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or healthcare provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.
Health Information Exchange (HIE)	Support Electronic Referral Loops by Receiving and Reconciling Health	Number of electronic summary of care records in the denominator for	Number of electronic summary of care records received using CEHRT for	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which

Objective	Measure	Numerator	Denominator	Exclusion
	Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.	which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: ● Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ASTP/ONC website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. ● Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.			
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a PHA to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2. Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no PHA has declared readiness to receive electronic case

Objective	Measure	Numerator	Denominator	Exclusion
				reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Public Health Registry Reporting (Optional Bonus): The MIPS eligible clinician is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting (Optional Bonus): The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting (Optional Bonus): The MIPS eligible clinician is in active engagement with a PHA to submit syndromic surveillance data from an urgent care setting.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Public Health Reporting Using TEFCA (Optional Bonus):* The MIPS eligible clinician is (1) participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on the ASTP/ONC website); (2) is not suspended from participating in TEFCA exchange; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (validated data production) with	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

Objective	Measure	Numerator	Denominator	Exclusion
	a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange with the PHA.			
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	Security Risk Analysis:* First, conduct or review a security risk analysis; and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include addressing the security of data created or maintained by CEHRT (to include encryption), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the MIPS eligible clinician would adopt an equivalent alternative measure if it is reasonable and appropriate to do so.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

Objective	Measure	Numerator	Denominator	Exclusion
Protect Patient Health Information	High Priority Practices SAFER Guide:* Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the High Priority Practices SAFER Guide measure using the 2025 High Priority Practices SAFER Guide during the year in which the performance period occurs.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

*Changes made to a measure in this final rule that are effective beginning with the CY 2026 performance period/2028 MIPS payment year.

(ii) Scoring Methodology for the CY 2026 Performance Period/2028 MIPS Payment Year

For reference, Table C-G3 sets forth the finalized scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, which includes the new optional bonus measure, Public Health Reporting Using TEFCA. When earning bonus points, a MIPS eligible clinician can receive a maximum of 5 points regardless of the number of bonus measures reported.

TABLE C-G3: SCORING METHODOLOGY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting****	25 points	Required
	Report one or more of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA*	5 points (*bonus*)	Optional
Protect Patient Health Information	Security Risk Analysis*	Not scored**	Required
	High Priority Practices SAFER Guide*	Not scored**	Required
No Associated Objective: Attestation Requirements***	ONC Direct Review Attestation	Not scored	Required
	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored	Required
	ONC-ACB Surveillance Attestation	Not scored	Optional

*The addition of the optional bonus measure, Public Health Reporting Using TEFCA, and the modifications to the Security Risk Analysis measure and the High Priority Practices SAFER Guide measure will be effective beginning with the CY 2026 performance period.
**MIPS eligible clinicians must submit an affirmative attestation regarding the Security Risk Analysis measure and the High Priority Practices SAFER Guide measure. Failure to submit an affirmative ("Yes") attestation to fulfill such requirements will result in a zero score for the MIPS Promoting Interoperability performance category.
***Attestation Requirements: MIPS eligible clinicians must submit an attestation regarding the ONC Direct Review and that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3). Failure to submit an attestation or an affirmative ("Yes") attestation to fulfill such requirements will result in a zero score for the MIPS Promoting Interoperability performance category.
****NOTE: The suppression of the Electronic Case Reporting measure only applies to the CY 2025 performance period/2027 MIPS payment year as discussed in section XX.X.x.(g). of this final rule and thus, it is not reflected in Table C-G3 as such table pertains to the CY 2026 performance period/2028 MIPS payment year and future years.

(iii) Point Redistribution

Many required measures have exclusions associated with them as set forth in Table C-G2 in this final rule. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available for each objective as displayed in Table C-G3 in this final rule do not include the points that would be redistributed if a MIPS

eligible clinician claims an exclusion for a specific measure. Table C-G4 in this final rule sets forth how points would be redistributed among the objectives and measures specified for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

TABLE C-G4: POINT REDISTRIBUTION FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange Under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure.

(iv) ONC Health IT Certification Criteria

Table C-G5 outlines the objectives and measures for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year and the associated ONC health IT certification criteria at 45 CFR 170.315 that are applicable for the CY 2026 performance period/2028 MIPS payment year. We refer readers to the CY 2024 PFS final rule (88 FR 79307 through 79312) for discussion of and amendments to the definition of CEHRT at § 414.1305.

TABLE C-G5: MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION CRITERIA

Objective	Measure	Certification Criteria (CY 2026 Performance Period/2028 MIPS Payment Year) in Title 45 of the CFR
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	§ 170.315(b)(1) Transitions of care
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation.
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange)	Examples of certified health IT capabilities to support the actions of this measure may include, but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation.
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Standardized API for patient and population services.
Health Information Exchange (alternative)	Enabling Exchange Under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include, but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care.
		§ 170.315(b)(2) Clinical information reconciliation and incorporation.
		§ 170.315(g)(7) Application access — patient selection.
		§ 170.315(g)(9) Application access — all data request.
		§ 170.315(g)(10) Standardized API for patient and population services.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	§ 170.315(e)(1) View, download, and transmit to 3rd party.
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Standardized API for patient and population services.
Public Health and Clinical Data Exchange	Immunization Registry Reporting	§ 170.315(f)(1) Transmission to immunization registries.
	Syndromic Surveillance Reporting (Optional)	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance.
	Electronic Case Reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting.
	Public Health Registry Reporting (Optional)	§ 170.315(f)(4)* Transmission to cancer registries
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys.
	Clinical Data Registry Reporting (Optional)	No health IT certification criteria at this time.
	Public Health Reporting Using TEFCA (Optional)	Examples of certified health IT capabilities to support the actions of this measure may include, but are not limited to technology certified to the following criteria:
		§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	High Priority Practices SAFER Guide	No health IT certification criteria at this time.

*In the CY 2026 PFS proposed rule, we inadvertently listed § 170.315(f)(6) "Transmission to public health agencies — antimicrobial use and resistance reporting" rather than § 170.315(f)(4) Transmission to cancer registries as the ONC Health IT certification criterion. Table C-G5 references the correct ONC Health IT certification criteria.

B. Additional CY 2026 Modifications to the Quality Payment Program

1. MIPS Final Score Methodology

a. Performance Category Scores

(1) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, provide for a final score for each MIPS eligible clinician. Section 1848(q)(6)(A) of the Act specifies that, to then determine a MIPS payment adjustment factor for each MIPS eligible clinician for an applicable MIPS payment year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. We refer readers to section IV.B.2. of this final rule for further discussion of the performance threshold, and our calculation of MIPS payment adjustment factors, and our proposals with respect thereto.

Section 1848(q)(2)(A) of the Act provides that the Secretary must assess each MIPS eligible clinician with respect to four performance categories in determining each MIPS eligible clinician's final score: quality, resource use (referred to as "cost"), clinical practice improvement activities (referred to as "improvement activities"), and meaningful use of certified EHR technology (referred to as "Promoting Interoperability"). Section 1848(q)(2)(B) of the Act describes the measures and activities that must be specified under each performance category. Section 1848(q)(3) of the Act provides that we must establish performance standards with respect to the measures and activities specified under the four performance categories for a performance period, considering historical performance standards, improvement, and the opportunity for continued improvement. To calculate a final score for each MIPS eligible clinician for the performance period of an applicable MIPS payment year, section 1848(q)(5)(A) of the Act provides that we must develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards we have established with respect to applicable measures and activities specified for each performance category, using a scoring scale of 0 to 100.

In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380.

Unless we assign a different scoring weight pursuant to these exceptions, for the CY 2026 performance period/2028 MIPS payment year, the scoring weights for each performance category are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

For the CY 2026 performance period/2028 MIPS payment year, we proposed to update our scoring methodologies to respond to statutory requirements and impacts observed in performance data (90 FR 32754 through 32762). Specifically, we proposed to—

- Modify the existing approach for identifying measures impacted by limited measure choice and subject to topped-out measure benchmarks by applying the existing analysis to MVPs;
- Apply defined topped out benchmarks for certain topped-out measures for clinicians impacted by limited measure choice; and
- Modify the benchmarking methodology for scoring administrative claims-based measures in the quality performance category.

The policies in this section of the final rule for scoring the quality performance category within traditional MIPS would apply to MVP scoring under § 414.1365(d)(3)(i) since a quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

We did not propose any changes to our scoring policies for the cost, improvement activities, or Promoting Interoperability performance categories.

(2) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure, and Administrative Claims Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules, and § 414.1380(b)(1) for our current policies regarding, among other things, quality measure benchmarks, calculating total measure achievement points, calculating the quality performance category score, including achievement and improvement points, the small practice bonus, and scoring flexibilities (81 FR 77276 through 77308, 82

FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, 87 FR 70088 through 70091, and 88 FR 79368 and 79369). In the CY 2025 PFS final rule (89 FR 98427 through 98439), we finalized policies for scoring topped-out measures in specialty measure sets with limited measure choice at § 414.1380(b)(1)(iv)(C) and (b)(1)(ii)(E) and a Complex Organization Adjustment for virtual groups and APM Entities at § 414.1380(b)(1)(vii)(C).

(a) Scoring for Topped-Out Measures with Limited Measure Choice

(i) Background on Scoring Topped-Out Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2023 and 2025 PFS final rules (81 FR 77282 through 77287, 82 FR 53721 through 53727, 83 FR 59761 through 59765, 88 FR 70090 and 70091, and 89 FR 98429 through 98435), and § 414.1380(b)(1)(iv) for established topped out measure scoring policies.

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (81 FR 77136). Section 1848(q)(3)(B) of the Act requires that in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. Topped out measures do not provide an opportunity for continued improvement, nor do payment adjustments based on topped out measures incentivize clinicians to improve their care. As a result, we finalized policies in the CY 2018 Quality Payment Program final rule (82 FR 53723 through 53727) to identify and cap the scoring potential of such measures. Additionally, we established practices for the removal of such measures, such as establishing the topped-out measure lifecycle, to continue to drive quality improvement in areas where such improvement is possible and necessary. The topped-out measure lifecycle is described in the CY 2018 Quality Payment Program final rule (82 FR 53721 and 53727). We established at § 414.1380(b)(1)(iv)(B) that we will cap scoring for topped-out measures at 7 measure achievement points in the second consecutive year that the measure benchmark is identified as topped out. If a measure has been identified as topped out for 3 consecutive years after being originally identified through the benchmarks, such measure may then be proposed for removal through notice-and-comment rulemaking (83 FR 59761). This timeline, however, is not fixed. We noted our concern that removal of

topped-out measures may leave clinicians with fewer than 6 applicable measures to report and that such removal in those instances will impact some specialties more than others (82 FR 53721). We stated that consideration for ensuring available applicable measures would be made when considering measure removals (83 FR 59763).

In the CY 2018 Quality Payment Program final rule (82 FR 53727), we established the topped-out scoring cap to encourage MIPS eligible clinicians to submit measures that are not topped out. However, we created an exemption to this policy in the CY 2025 PFS final rule (89 FR 98430) for certain measures, which are frequently used by certain specialties impacted by limited measure choice. To address scoring scenarios in which limited measure choice compels clinicians to report topped-out measures with scoring caps, we finalized in the CY 2025 PFS final rule (89 FR 98429 through 98432) at § 414.1380(b)(1)(iv)(C) that beginning with the CY 2025 performance period/2027 MIPS payment year, topped-out measures frequently used by certain specialties reporting specialty measure sets that are impacted by limited measure choice (specified in accordance with § 414.1380(b)(1)(ii)(E)) are not subject to the 7-point scoring cap. As part of the CY 2025 PFS final rule, we finalized at § 414.1380(b)(1)(ii)(E) that beginning with the CY 2025 performance period/2027 MIPS payment year, we will annually publish a list in the **Federal Register** of topped-out measures determined to be impacted by limited measure choice (89 FR 98432). Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped-out measure benchmarks calculated from performance data in the baseline period, in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

In the CY 2025 PFS final rule (89 FR 98432 through 98435), we also finalized our approach for identifying the list of measures impacted by limited measure choice and subject to defined topped-out measure benchmarks. Specifically, we finalized that each specialty measure set is reviewed by collection type to identify if the prevalence of topped-out measures within such a set hinders a clinician's ability to successfully participate in the MIPS quality performance category. To make such a determination, we finalized that we analyze the ability of clinicians reporting the specialty measure sets under review to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements. Specifically, at the collection type level, each measure is assigned

points based upon the current benchmarking data: new measures receive 7 or 5 points based on year in the program, measures with benchmarks are given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark are given 0 points. All measure set points are added together to get an output of scoring potential; the Medicare Part B claims collection type measure sets have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each measure set are then compared to the analysis threshold, which is currently 75 percent of available quality achievement points, based upon the number of available measures. Any measure sets that are not able to meet or exceed the threshold are flagged as 'at-risk.' Additional factors that we take into consideration include whether the topped-out measure within the specialty measure set under review is considered a cross-cutting measure or is a broadly applicable measure, which we consider to be a measure included in three or more specialty sets. We also consider in reviewing topped-out measures within a specialty measure set whether the specialty measure set contains more than ten measures, by collection type (89 FR 98432 through 98435).

(ii) Measures to be Subject to the Defined Topped-Out Measure Benchmark for the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2026 PFS proposed rule (90 FR 32754 through 32756), beginning with the CY 2026 performance period/2028 MIPS payment year, we proposed to modify the previously finalized approach for identifying measures impacted by limited measure choice (89 FR 98432 through 98435) by applying the analysis and criteria to MVPs, in addition to the analysis of specialty measure sets. For the CY 2026 performance period/2028 MIPS payment year, we also proposed in the CY 2026 PFS proposed rule (90 FR 32754 through 32756) to continue to use an analysis threshold of 75 percent of available quality achievement points in our determination of which measures would not be subject to the 7-measure achievement point cap, reflecting the MIPS payment adjustment performance threshold of 75 points. We refer readers to section IV.B.2.b.(2) of this final rule where we finalize a performance threshold of 75 points for the CY 2026 through CY 2028 performance periods/2028 through 2030 MIPS payment years.

MVPs, like specialty measure sets, contain a limited set of quality measures for a clinician to choose from. We have received feedback from interested parties and independently verified that clinicians

reporting MVPs in which there is high presence of topped-out measures receiving the 7-point cap are often facing both limited measure choice and limited scoring opportunities. Given the limited number of available measures, the prevalence of topped-out measures within an MVP may similarly hinder a clinician's ability to successfully participate in the MIPS quality performance category. Using the same methodology applicable to topped-out measures within specialty measure sets, we proposed to conduct an analysis of each MVP to identify if the prevalence of topped-out measures within such MVP hinders a clinician's ability to successfully participate in the MIPS quality performance category. According to the approach finalized in the CY 2025 PFS final rule for specialty measure sets (89 FR 98432 through 98435), at the collection type level, each quality measure in an MVP would be assigned points based upon the current benchmarking data: new measures would receive 7 or 5 points based on year in the program, measures with benchmarks would be given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark would be given 0 points. All points would be added together to get an output of scoring potential; the Medicare Part B claims collection type measures would have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each MVP would be compared to the analysis threshold, which is currently 75 percent of available quality achievement points, based upon the number of available measures. Any MVPs that are not able to meet or exceed the threshold would be flagged as 'at-risk.' Additional factors that we would take into consideration would include whether the topped-out measure within the MVP under review is considered a cross-cutting measure or is a broadly applicable measure, which we would consider to be a measure included in three or more MVPs or specialty sets. We would also consider when reviewing topped-out measures within an MVP whether the MVP contains more than ten measures, by collection type.

Table C-I1 contains the list of measures that meet the criteria for topped-out measures impacted by limited measure choice in specialty measure sets and MVPs, and for which we proposed in the CY 2026 PFS proposed rule (90 FR 32756 and 32757) to apply the defined topped-out measure benchmark for the CY 2026 performance period/2028 MIPS payment year. We had considered proposing MIPS CQM 424: Perioperative Temperature Management to be subject to the defined topped-out measure

benchmark for the CY 2026 performance period/2028 MIPS payment year since it met the criteria for topped-out measures in specialty measure sets impacted by limited measure choice, according to the methodology finalized in the CY 2025 PFS final rule (89 FR 98432 through 98435). However, we did not propose that measure for the defined topped-out measure benchmark for the CY 2026 performance period/2028 MIPS payment year because it was proposed for removal for the CY 2026 performance period/2028 MIPS payment year in the CY 2026 PFS proposed rule (90 FR 32717). We refer readers to section IV.A.4.d.(1)(c)(ii) of this final rule for discussion of the quality performance category measure inventory.

TABLE C-I1: TOPPED-OUT MEASURES IMPACTED BY LIMITED MEASURE CHOICE AND SUBJECT TO DEFINED TOPPED-OUT MEASURE BENCHMARKS FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Measure ID	Collection Type	Measure Title
141	Medicare Part B Claims	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care
143	eCQM, MIPS CQM	Oncology: Medical and Radiation - Pain Intensity Quantified
144	MIPS CQM	Oncology: Medical and Radiation - Plan of Care for Pain
249	Medicare Part B Claims, MIPS CQM	Barrett's Esophagus
250	Medicare Part B Claims, MIPS CQM	Radical Prostatectomy Pathology Reporting
320	Medicare Part B Claims	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
350	MIPS CQM	Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy
351	MIPS CQM	Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
360	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
364	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
395	Medicare Part B Claims, MIPS CQM	Lung Cancer Reporting (Biopsy/Cytology Specimens)
396	MIPS CQM	Lung Cancer Reporting (Resection Specimens)
397	Medicare Part B Claims, MIPS CQM	Melanoma Reporting
405	MIPS CQM	Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Measure ID	Collection Type	Measure Title
406	Medicare Part B Claims, MIPS CQM	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients
430	MIPS CQM	Prevention of Post-Operative Nausea and Vomiting (PONV) - Combination Therapy
440	MIPS CQM	Skin Cancer: Biopsy Reporting Time - Pathologist to Clinician
463	MIPS CQM	Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics)
477	MIPS CQM	Multimodal Pain Management

We solicited comments on the following proposals beginning with the CY 2026 performance period/2028 MIPS payment year: (1) include MVPs in the analysis used to identify the list of topped-out measures impacted by limited measure choice ; (2) continue using an analysis threshold of 75 percent of available quality achievement points in our determination of which measures would be subject to the defined topped-out measure benchmark; and (3) list of topped-out measures impacted by limited measure choice and subject to the defined topped-out measure benchmark.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to identify topped-out measures impacted by limited measure choice in specialty measure sets and MVPs. Several commenters supported the proposed list of measures subject to the defined topped-out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

Response: We thank commenters for their support.

Comment: Several commenters expressed concerns with the methodology CMS uses to identify topped-out measures in specialty measure sets and MVPs as "at risk" and, therefore, eligible for the defined topped-out measure benchmark. A few commenters urged CMS to assess the issue of limited measure choice at the subspecialty level, citing concern that assessing only at the specialty level does not address scenarios where subspecialists may have a limited number of clinically relevant, non-topped-out measures available to them. A commenter recommended that CMS apply a subspecialty analysis to MVPs as well as to specialty sets to evaluate whether all types of clinicians who could report a specific MVP could succeed based on the available measures in the MVP. A commenter urged CMS to incorporate additional factors into the decision, including clinical relevance, patient impact, and alignment with value-

based care principles. A commenter recommended that CMS set a 2-year timeframe for reevaluating measures selected for the list of topped-out measures impacted by limited measure choice.

Response: The defined topped-out measure benchmark policy seeks to provide scoring relief for clinicians whose MIPS performances are most impacted by limited measure choice and who would otherwise be unable to avoid a negative payment adjustment due to limited measure choice and the topped-out measure scoring cap. The policy evaluates specialty measure sets and MVPs because these are defined measure sets that may contain fewer measures for certain clinicians to choose from. We do not conduct analysis at the subspeciality level because subspecialties do not have a defined set of measures in the Quality Payment Program. While this policy focuses on addressing measures with topped out status for specialties with limited measure choice, we consider clinical relevance, patient impact, and value-based care principles in our maintenance of the quality measure inventory. We will continue to monitor the impacts of this policy on clinicians' ability to meaningfully participate in MIPS.

We do not apply the defined topped-out measure benchmarks for a 2-year timeframe because measure performance varies each year, and thus a measure's topped out status may change each year.

Comment: A few commenters recommended that the defined topped-out measure benchmark apply to all topped-out measures, stating their belief that limiting the policy to selected measures is arbitrary, adds complexity, and favors some specialties over others. Several commenters specifically requested that CMS apply the defined topped-out measure benchmark to additional measures. Several commenters requested that the hospitalist measure set be added to the defined topped-out measure benchmark policy, stating that all four measures in the specialty set are topped out which places hospitalist clinicians at a disadvantage in the MIPS program, as they also may have the Promoting Interoperability and cost performance categories reweighted. A few commenters recommended that QCDR measures should be included in the defined topped-out measure benchmark policy. A commenter requested that several podiatry measures be scored according to defined topped-out measure benchmarks.

Response: As discussed in section XX of this final rule, topped-out measures are measures with performance so high and unvarying that meaningful distinctions and improvements in performance can no longer be made, the measures do not provide an opportunity for continued improvement, and payment adjustments based on topped-out measures do not incentivize clinicians to improve their care. We cap

scoring for topped-out measures at 7 measure achievement points in the second consecutive year that the measure benchmark is identified as topped out to incentivize clinicians to report measures for which continued improvement is still possible. The topped-out measure scoring cap is a useful tool for communicating that there is limited opportunity for continued quality improvement. Clinicians without limited measure availability can choose to report measures that are not topped out and for which they can receive up to 10 measure achievement points.

This policy aims to identify measures impacted by limited measure choice and apply defined topped-out measure benchmarks to only those measures, while retaining the 7-point scoring cap for topped-out measures that are not impacted by limited measure choice.

Topped-out measures in the hospitalist specialty measure set were not proposed to be scored according to the defined topped-out measure benchmark because the measures are cross-cutting or broadly applicable. In accordance with CMS' established methodology, as stated in the CY 2025 PFS final rule (89 FR 98432 through 98435), additional factors CMS takes into consideration in determining which measures may be subject to defined topped out measure benchmarks include whether the topped out measure within the specialty measure set is considered a cross-cutting measure or is a broadly applicable measure. Cross-cutting quality measures are broadly applicable to all clinicians regardless of their specialty; broadly applicable measures are those included in three or more specialty sets. We do not include such measures in the defined topped-out measure benchmark policy in order to retain the 7-point topped-out measure scoring cap for clinicians who do not experience limited measure choice. Measures in the podiatry specialty measure set were not proposed to be scored according to the defined topped-out measure benchmark because the specialty measure set did not meet the criteria for being 'at risk' of not meeting the performance threshold of 75 due to limited measure choice and the topped-out measure scoring cap. We will continue to monitor the topped-out status of measures in the podiatry specialty measure set to determine if proposed inclusion in the defined topped-out measure benchmark policy is warranted in future years.

QCDR measures were not included in the scope of this policy because they are governed by another policy at § 414.1400(b)(4)(iii)(C) stating that CMS may revoke a measure's second year approval if identified as topped out.

Comment: Several commenters expressed concerns about the overall impact of the scoring cap for topped-out measures, especially for specialties with a limited number of available measures such as physical therapy, physical medicine and rehabilitation, and gastroenterology. A few commenters recommended that CMS comprehensively reevaluate the scoring methodology for topped-out measures.

Response: The 7-point scoring cap for topped-out measures seeks to incentivize clinicians to report measures for which meaningful distinctions in performance can be made and continued improvement is still possible. We did not propose measures in the physical therapy or physical medicine specialty measure sets to be scored according to defined topped-out measure benchmarks because the "at-risk" topped-out measures are either cross-cutting or in three or more specialty measure sets. In Table C-I1 we proposed one measure in the gastroenterology specialty measure set to be scored according to the defined topped-out measure benchmark (Medicare Part B Claims Measure 320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients), however we did not propose additional topped-out gastroenterology measures because the "at-risk" measures are cross-cutting. We will evaluate the impact of our scoring policies and consider scoring alternatives for topped-out measures.

Comment: A few commenters recommended that CMS refine the defined topped-out measure benchmark by removing the lowest decile instead of the ninth because they believe it will result in more consistent and fair scoring.

Response: We clarify that the defined topped-out measure benchmark does not remove any decile and contains 10 deciles. In the CY 2025 PFS final rule (89 FR 98429 through 98432), we discussed that we proposed to remove the ninth decile for the defined topped-out measure benchmark, however, that policy was not finalized. We finalized the defined topped-out measure benchmark to include the 9th decile, which corresponds to a performance rate from 99 to 99.9 percent.

Comment: A commenter opposed allowing selected specialties to earn full quality measure achievement points when reporting topped-out measures, expressing skepticism that the MIPS quality measure inventory does not include measures that could apply to specialists. The commenter believes that this policy sends a mixed message about the importance of meeting high quality standards.

Response: To identify measures for the defined topped-out measure benchmark policy, we evaluate the ability of clinicians reporting specialty measure sets and MVPs to achieve the performance

threshold because clinicians reporting specialty measure sets and MVPs have fewer measures from which to choose. The policy seeks to limit the scoring relief to only those who would otherwise receive a negative payment adjustment only due to limited measure choice and the topped-out scoring cap. The defined topped-out measure benchmark distribution is intended to encourage high performance and clinical quality improvement by having a performance rate of 97 percent correspond to 7.5 achievement points for the CY 2026 performance period/2028 MIPS payment year.

Comment: A commenter expressed concern that two oncology quality measures, Quality ID 143: Oncology: Medical and Radiation -Pain Intensity Quantified (eCQM, MIPS CQM) and Quality ID 144: Oncology: Medical and Radiation -Plan of Care for Pain (MIPS CQM) were proposed to receive topped-out measure benchmarks for the 2026 MIPS performance period. The comment stated that the measures continue to be meaningful and should be reported and expressed the concern that without these two measures, radiation oncologists would only have two reportable measures in the specialty set.

Response: We clarify that measures included in this proposal would not be removed from the specialty measure set and would be available for clinicians to report. Topped-out measures included in this proposal would have the 7-point scoring cap removed and be scored according to the defined topped-out measure benchmark.

After consideration of public comments, we are finalizing as proposed to include MVPs in the analysis used to identify the list of topped-out measures impacted by limited measure choice beginning with the CY 2026 performance period/2028 MIPS payment year. We are also finalizing as proposed to continue using an analysis threshold of 75 percent of available quality achievement points in our determination of which measures would be subject to the defined topped-out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

We are also finalizing as proposed the list of topped-out measures impacted by limited measure choice and subject to the defined topped-out measure benchmark for the CY 2026 performance period/2028 MIPS payment year.

(b) Benchmark Methodology for Scoring Administrative Claims-based Quality Measures in the Quality Performance Category

(i) Background on Scoring Administrative Claims Measures in the Quality Performance Category

At § 414.1325, we specify that there is no data submission requirement for cost measures or administrative claims measures in the quality performance category as these measures are calculated on behalf of participants by CMS using administrative claims data. CMS calculates MIPS eligible clinicians' performance on these measures using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period. In the CY 2017 Quality Payment Program final rule (81 FR 77130), we finalized a policy that clinicians would be scored on applicable administrative claims-based global or population health (henceforth referred to only as population health measures) in addition to the six required submitted quality measures. We refer readers to the CY 2017 Quality Payment Program final rule and the CY 2021 PFS final rule (81 FR 77130 through 77136 and 85 FR 84871 through 84873, respectively) and § 414.1325(a)(2)(i) for our previously established policies regarding administrative claims measures in the quality performance category.

We have codified our quality performance category scoring policies at § 414.1380(b)(1). Under § 414.1380(b)(1)(i), except as provided under paragraph (b)(1)(i)(C) beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) based on their performance on each measure. At § 414.1380(b)(1)(i)(A)(*2*)(*ii*), each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points.

We also refer readers to the CY 2017, CY 2018, CY 2019 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, and 83 FR 59841 through 59842, respectively) and CY 2020, CY 2021, and CY 2023 PFS final rules (84 FR 63014 through 63016, 85 FR 84901 through 84904, and 87 FR 70088 through 70090, respectively) for our previously established benchmarking policies.

In the CY 2017 Quality Payment Program final rule (81 FR 77276 through 77282), we finalized that we will use MIPS eligible clinicians' performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or quality measures where we do not have comparable data from the baseline period. In

these cases, we will calculate benchmarks using data submitted during the applicable performance period. We defined the baseline period to be the 12-month Calendar Year that is 2 years prior to the performance period for the MIPS payment year.

Moreover, in the CY 2023 PFS final rule (87 FR 70088 through 70090), we finalized beginning with the CY 2023 performance period/2025 MIPS payment year, that we would score administrative claims measures using performance period benchmarks (§ 414.1380(b)(1)(ii)(D)). We stated that we believe that using a performance period benchmark to score these measures would allow for scores that are more reflective of current performance, while adding no additional burden to clinicians.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77282), we establish benchmarks as a standardized method to evaluate and compare the performance of quality measures relative to the performance of peers. We use a decile-based approach to create benchmarks, which is done by dividing measure performance rates into deciles, with each decile containing a range of performance rates. CMS assigns measure achievement points based on which benchmark decile range the measure performance rate falls between. CMS assigns partial points to prevent performance cliffs for performance rates near the decile breaks. Additionally, the four administrative claims-based quality measures currently available to MIPS eligible clinicians are inverse measures, meaning the lower the measure performance rate, the higher the measure achievement points. Therefore, lower benchmark deciles are associated with higher performance rates. MIPS eligible clinicians with higher performance rates of administrative claims-based measures (for example, the number of acute unplanned cardiovascular-related admissions per 100 person-years at risk for admission during the measurement period) will have rates that fall into lower benchmark deciles and will score fewer measure points than MIPS eligible clinicians with lower measure performance rates.

TABLE C-I2: EXAMPLE OF USING DECILE-BASED BENCHMARK AND PARTIAL POINTS TO ASSIGN ACHIEVEMENT POINTS FOR PERFORMANCE ON THE RISK-STANDARDIZED ACUTE CARDIOVASCULAR-RATED HOSPITAL ADMISSION RATES FOR PATIENTS WITH HEART FAILURE UNDER THE MERIT-BASED INCENTIVE PAYMENT SYSTEM ADMINISTRATIVE CLAIMS-BASED QUALITY MEASURE

Benchmark Decile	Example Benchmark Ranges (Performance Rate)	Possible Points
Benchmark Decile 1	81.68-75.77	1.0–1.9
Benchmark Decile 2	75.76-73.44	2.0-2.9
Benchmark Decile 3	73.43-71.92	3.0-3.9
Benchmark Decile 4	71.91-70.81	4.0-4.9
Benchmark Decile 5	70.80-69.72	5.0-5.9
Benchmark Decile 6	69.71-68.79	6.0-6.9
Benchmark Decile 7	68.78-67.72	7.0-7.9
Benchmark Decile 8	67.71-66.51	8.0-8.9
Benchmark Decile 9	66.50-64.97	9.0-9.9
Benchmark Decile 10	64.96 and below	10

Table C-I2 provides an example of using benchmark deciles along with partial achievement points to assign achievement points for the Risk-standardized Acute Cardiovascular-rated Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System administrative claims-based quality measure under our current methodology. For this measure, that outcome is the number of acute unplanned cardiovascular-related admissions per 100 person-years at risk for admission during the measurement period. Additionally, this measure is an inverse measure. The following formula is used to determine the number of partial points awarded to the MIPS eligible clinician:

Benchmark Decile # + [(performance rate – bottom of benchmark decile range) / (top of benchmark decile range – bottom of benchmark decile range)] = Quality Measure Achievement Points.

For the example measure presented in Table C-I2, the median performance rate is 69.71, which falls within Benchmark Decile 6. If a MIPS eligible clinician's performance rate for the measure is 73.82, the MIPS eligible clinician's performance rate falls within Benchmark Decile 2, for which the MIPS eligible clinician may receive between 2.0 and 2.9 achievement points. Based on the partial points calculation formula, the clinician would receive 0.83 partial points, resulting in a quality measure score of 2.83 out of 10 achievement points for the administrative claims-based quality measure under this example.

Based on our analysis of quality measure scores for the CY 2022 performance period/2024 MIPS payment year, we observed lower scores for the administrative claims-based quality measures than for the non-administrative claims-based quality measures. Means for administrative claims-based quality measure achievement scores tend to be around 5 to 6 points out of 10, whereas means for non-administrative claims-based measures tend to be around 7 to 9 points out of 10.

There are key factors that may contribute to lower measure scores for the administrative claims-based measures, compared to the other quality measures. First, administrative claims-based quality measures are scored against a performance period benchmark, rather than a benchmark determined based on historical data, which is used, wherever possible, for non-administrative claims-based quality measures. Benchmarks established based on historical data provide MIPS eligible clinicians with helpful performance targets in advance of or during the performance period. Meanwhile, the performance period benchmarks for the administrative claims-based quality measures do not provide information about performance targets before or during the performance period. However, since these measures require no data submission, using performance period benchmarks allows for the calculation of more current and representative measure scores that better track clinician performance and progress over time. We are concerned that the current decile-based, performance period benchmark is a key contributor to lower scores for the administrative claims-based quality measures. Specifically, the current quality benchmark methodology uses a decile range based on linear percentile distributions and assigns 5.0 to 6.9 achievement points to clinicians with measure performance rates within the 50th to 60th percentiles. As a result, clinicians who perform around the median on administrative claims-based measures will receive achievement points below 7.5 points, the equivalent of the performance threshold.

Second, in traditional MIPS, MIPS eligible clinicians are scored on each administrative claims-based quality measure for which the established case minimum is met, and a benchmark can be calculated. Further, not all MIPS eligible clinicians are scored on administrative claims-based quality measures. Therefore, if a clinician is scored on one or multiple administrative claims-based quality measures with measure achievement scores around 5 to 6 points out of 10, these measure scores may have the effect of lowering the MIPS eligible clinician's quality performance category score, especially in comparison to a clinician who is not scored on any administrative claims-based quality measure.

(ii) Background on Scoring Measures in the Cost Performance Category

In the CY 2025 PFS final rule (89 FR 98438 through 98446), we addressed concerns raised by MIPS eligible clinicians about cost performance category scoring having a negative impact on their final MIPS score. We noted how, under the cost scoring methodology for the CY 2017 performance period/2019 MIPS payment year through the CY 2023 performance period/ 2025 MIPS payment year, a MIPS eligible clinician scoring near the median on a cost measure would need to score perfectly (or nearly perfectly) within the other three performance categories to receive a final score slightly above the performance threshold and to avoid a negative payment adjustment (89 FR 98439 through 98442). To address this concern, we modified the methodology for scoring the cost performance category, as set forth at § 414.1380(b)(2), beginning with the CY 2024 performance period/2026 MIPS payment year (89 FR 98441 through 98446; 89 FR 98563).

The cost scoring methodology we finalized at § 414.1380(b)(2) is now based on standard deviation, median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose average costs attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians that had the measure attributed them, we assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2024 performance period/2026 MIPS payment year, if a MIPS eligible clinician's average costs under the measure is equal to the median costs of all MIPS eligible clinicians attributed the same measure, then we assign the MIPS eligible clinician 7.5 achievement points, based on a performance threshold of 75 as finalized at § 414.1405(b)(9)(iii). For each cost measure, the cut-offs for benchmark ranges are calculated based on standard deviations, expressed in dollars, from the median. We refer readers to Table C-I3 for an example of how the cost scoring methodology could be implemented for a specific cost measure when the performance threshold is set to 75 points, which is the same example we provided in the CY 2025 PFS final rule (89 FR 98441 and 98442).

TABLE C-I3: EXAMPLE OF IMPLEMENTATION OF THE PROPOSED COST SCORING METHODOLOGY FOR ASSIGNMENT OF ACHIEVEMENT POINTS FOR PERFORMANCE ON THE SCREENING/SURVEILLANCE COLONOSCOPY COST MEASURE

Benchmark Range	Points	Proposed Methodology for Bottom of Benchmark Range ($)	Example Benchmark Ranges
Benchmark Range 1	1 - 1.9	Median cost + (2.75 x standard deviation)	$1341.93 - $1308.10
Benchmark Range 2	2 - 2.9	Median cost + (2.5 x standard deviation)	$1308.09 - $1.274.26
Benchmark Range 3	3 - 3.9	Median cost + (2.25 x standard deviation)	$1274.25 - $1240.43
Benchmark Range 4	4 - 4.9	Median cost + (2 x standard deviation)	$1240.42 - $1172.75
Benchmark Range 5	5 - 5.9	Median cost + (1.5 x standard deviation)	$1172.74 - $1105.08
Benchmark Range 6	6 – 6.9	Median cost + (1 standard deviation)	$1105.07 - $1037.40
Benchmark Range 7	7 - 7.9	Median cost + (0.5 x standard deviation)	$1037.39 - $902.05
Benchmark Range 8	8 - 8.9	Median cost - (0.5 x standard deviation)	$902.04 - $834.38
Benchmark Range 9	9 - 9.9	Median cost - (1 x standard deviation)	$834.37 - $766.70
Benchmark Range 10	10	Median cost - (1.5 x standard deviation)	$766.69 and below

This modification in our scoring methodology for cost measures aligns the assignment of achievement points for cost measures so that clinicians with costs near the measure's 50th percentile (median) do not receive a disproportionately low score. Our intended goal for this modification to the scoring methodology was to ensure that MIPS eligible clinicians who deliver care at an average cost near the median costs for all MIPS eligible clinicians attributed the measure receive scores at, or very close to, the performance threshold-derived score (89 FR 98442 and 98443). Additionally, this modification addressed MIPS eligible clinicians' concerns that cost measure scoring negatively impacts their final scores more than other performance categories, including disparate negative effects for MIPS eligible clinicians who are scored on the cost performance category compared to clinicians not scored on the cost performance category (89 FR 98443).

(iii) Modification to Scoring Methodology for Administrative Claims-based Quality Measures in the Quality Performance Category Beginning with CY 2025 Performance Period/2027 MIPS Payment Year

Given the similarities between scoring cost measures and administrative claims-based quality measures, we proposed to modify the methodology for scoring the administrative claims-based measures within the quality performance category beginning with the CY 2025 performance period/2027 MIPS payment year (90 FR 32762). The proposed administrative claims-based quality measure scoring methodology would be based on standard deviation, median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose performance rate under an administrative claims-based measure would be equal to the median performance rate for all MIPS eligible clinicians that are scored on that measure, we would assign an achievement point value

equal to 10 percent of the performance threshold. For example, for the CY 2026 performance period/2028 MIPS payment year, the median would have an achievement point value of 7.5, based on a performance threshold of 75 points as finalized in section IV.B.2.b.(2) of this final rule. For each administrative claims-based quality measure, the cut-offs for benchmark ranges would be calculated based on standard deviations from the median.

The benchmark ranges, the median, and the performance threshold-derived achievement point values aligned with the median would be dynamic and responsive to changes in performance rates assessed by administrative claims-based quality measures and performance thresholds for each CY performance period/MIPS payment year. The performance threshold-derived point values could change based on the performance threshold established for each performance period/MIPS payment year. The standard deviations from the median used to determine cutoffs for benchmark ranges for each year would be reviewed for any necessary updates on an annual basis based on performance across MIPS eligible clinicians and the performance threshold established for the performance period/MIPS payment year. We would perform analyses when the performance threshold changes to set the benchmark ranges. To determine the benchmark ranges, we will adhere to the following principles: (1) center the majority of performance rates around the performance threshold-derived point value; (2) determine benchmark ranges according to the statistical distribution curve of the performance rate; and (3) distribution of achievement points for administrative claims-based quality measures should be reflective of overall program performance. We refer readers to Table C-I4 for an example of how the proposed administrative claims-based quality measure scoring methodology could be implemented for a specific quality measure when the performance threshold is set to 75 points.

TABLE C-I4: EXAMPLE OF IMPLEMENTATION OF THE SCORING METHODOLOGY FOR ASSIGNMENT OF ACHIEVEMENT POINTS FOR PERFORMANCE ON THE RISK-STANDARDIZED ACUTE CARDIOVASCULAR-RATED HOSPITAL ADMISSION RATES FOR PATIENTS WITH HEART FAILURE UNDER THE MERIT-BASED INCENTIVE PAYMENT SYSTEM ADMINISTRATIVE CLAIMS-BASED QUALITY MEASURE

Benchmark Range	Points	Methodology for Bottom of Benchmark Range	Example Benchmark Ranges (Performance Rate)
Benchmark Range 1	1 - 1.9	Median Performance Rate + (2.75 x standard deviation)	81.77-80.69
Benchmark Range 2	2 - 2.9	Median Performance Rate + (2.5 x standard deviation)	80.68-79.59
Benchmark Range 3	3 - 3.9	Median Performance Rate + (2.25 x standard deviation)	79.58-78.49
Benchmark Range 4	4 - 4.9	Median Performance Rate + (2 x standard deviation)	78.48-76.30
Benchmark Range 5	5 - 5.9	Median Performance Rate + (1.5 x standard deviation)	76.29-74.10
Benchmark Range 6	6 – 6.9	Median Performance Rate + (1 standard deviation)	74.09-71.92
Benchmark Range 7	7 - 7.9	Median Performance Rate + (0.5 x standard deviation)	71.91-67.53
Benchmark Range 8	8 - 8.9	Median Performance Rate - (0.5 x standard deviation)	67.52-65.34
Benchmark Range 9	9 - 9.9	Median Performance Rate - (1 x standard deviation)	65.33-63.15
Benchmark Range 10	10	Median Performance Rate - (1.5 x standard deviation)	63.14 and below

Continuing with the Risk-standardized Acute Cardiovascular-rated Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System administrative claims-based quality measure example, now presented in Table C-I4 as an example of implementation of the proposed scoring methodology, the median (50th percentile) performance rate would remain 69.71. Under the proposed scoring methodology, for the CY 2025 performance period/2027 MIPS payment year, a MIPS eligible clinician with a performance rate equal to the median performance rate of all MIPS eligible clinicians scored on that measure would receive 7.5 achievement points out of 10 possible achievement points, which falls within the Benchmark Rage 7 in Table C-I4.

Using the same example as previously presented in section IV.B.1.a.(2)(b)(i) of this final rule, we would apply the proposed scoring benchmark methodology as shown in Table C-I4 to a MIPS eligible clinician with a performance rate for this measure that is 73.82 (a rate of 4.11 above the median rate). Based on the analysis of data in this example, the standard deviation for the example administrative claims-based quality measure would be 4.38. This value for the standard deviation would then be used to calculate the benchmark ranges in Table 69 by plugging in this value for the standard deviation for each benchmark range. For example, "69.71 + (1 x 4.38)" would be calculated for "Median performance rate + (1 standard deviation)" for the bottom of Benchmark range 6. As shown with the example in Table C-I4, under our proposed scoring methodology, the MIPS eligible clinician's average performance rate of

73.82 percent would fall within Benchmark Range 6 for the example administrative claims-based quality measure, for which the MIPS eligible clinician may receive between 6.0 and 6.9 achievement points.

In alignment with the cost measure scoring methodology finalized last year (89 FR 98563), this proposed scoring methodology for administrative claims-based quality measures would be based on standard deviation, median, and an achievement point value derived from the performance threshold. For each administrative claims-based quality measure, standard deviations would be used to calculate the benchmark ranges which are then used to determine the measure scores for each MIPS eligible clinician scored on that measure based on their measure performance rate.

Under our proposal to modify the administrative claims-based quality measure scoring methodology for individual measures, we would continue to use our established formula to assign partial achievement points:

Benchmark Range # + [(performance rate – bottom of benchmark range) / (top of benchmark range – bottom of benchmark range)] = Administrative Claims-based Quality Measure Achievement Points.

As a result, using the example shown in Table C-I4, under our proposed administrative claims-based scoring methodology, the MIPS clinician would receive 6.12 quality measure achievement points (6 + [(73.82- 74.09) / 71.92- 74.09)] = 6.12). The assignment of 6.12 achievement points under the proposed administrative claims-based quality measure scoring methodology would be closer to the performance threshold equivalent of 7.5 than the assignment of 2.83 achievement points under the current scoring methodology, as discussed in our previous example in section IV.B.1.a.(2)(b)(i) of this final rule.

This proposed modification in our scoring methodology for administrative claims-based quality measures would align the assignment of achievement points for such measures so that clinicians with performance rates near the measure's 50th percentile (median) would not receive a disproportionately low score. Based on our analysis utilizing data from the CY 2024 performance period/2026 MIPS payment year, this proposed methodology would increase the mean quality performance category score from 76.75 out of 100 to 80.42 out of 100 (an increase of 3.67 points). Further, this proposed scoring methodology would increase the means for each administrative claims-based quality measure score by amounts ranging from 1.46 to 1.96 points. For example, the mean measure score for the Risk-Standardized Acute

Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System administrative claims-based quality measure would increase from 5.59 points out of 10 to 7.05 points out of 10. Our analyses showed that, under the proposed methodology, the mean final score would increase by 1.63 points for MIPS eligible clinicians assessed on at least one administrative claims-based quality measure and receiving a quality performance category score.

Specifically, our analyses support the intended goal for the proposed modification to the scoring methodology: MIPS eligible clinicians who perform near the median performance rate for all MIPS eligible clinicians scored on the administrative claims-based measure would receive scores at, or very close to, the performance threshold-derived score. Additionally, the proposed modification would align the scoring methodologies for administrative claims-based measures in the quality and cost performance categories.

We also proposed to modify § 414.1380(b)(1)(i) to specify that, except as specified otherwise under paragraph (b)(1)(ii), the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. We did not propose any modifications to the remainder of the language currently at § 414.1380(b)(1)(i).

We also proposed to codify benchmarking methodology at § 414.1380(b)(1)(ii)(D) to specify that beginning with the CY 2025 performance period/2027 MIPS payment year, for each administrative claims-based quality measure, CMS determines 10 benchmark ranges based on the median performance rate of all MIPS eligible clinicians scored on the measure, plus or minus standard deviations and that CMS awards achievement points based on which benchmark range a MIPS eligible clinician's performance rate for an administrative claims-based quality measure corresponds. We also proposed to codify at § 414.1380(b)(1)(ii)(D) that, beginning with the CY 2025 performance period/2027 MIPS payment year, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose performance rate is equal to the median performance for all MIPS eligible clinicians scored on the measure.

We solicited comments on our proposals to modify our scoring methodology for administrative claims-based quality measures. We also solicited comments on our proposal to codify the scoring

methodology for administrative claims-based quality measures in the quality performance category at § 414.1380(b)(1)(i) and (b)(1)(ii)(D).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to modify the benchmarking methodology for administrative claims-based quality measures to align with the benchmarking methodology used for cost measures, starting with the CY 2025 performance period/2027 MIPS payment year. Many commenters believe that the proposed methodology change would enhance fairness, promote a more consistent, equitable, and statistically sound scoring process, and improve clinician confidence in the MIPS program. Specifically, several commenters supported the proposal to assign an achievement point value equal to 10 percent of the performance threshold for clinicians whose performance rate equals the median and stated their belief that this adjustment better reflects average performance and helps ensure that clinicians are not penalized for falling near the statistical center of the distribution. Several commenters noted that the current decile-based benchmark methodology for administrative claims-based measures may result in disproportionately lower scores compared to non- administrative-claims-based measures and noted their belief that this discrepancy undermines the fairness and consistency of MIPS scoring and may inadvertently penalize clinicians—particularly small practice and primary care physicians—who rely on administrative claims-based measures due to limited reporting options or practice infrastructure. A commenter expressed their belief that the proposed approach better reflects how most clinicians are performing, without giving an unfair boost to top outliers.

Response: We thank the commenters for their support.

Comment: Several commenters suggested that CMS apply the proposed benchmarking methodology to all quality measures, not only administrative claims measures. A few commenters believe that the proposed methodology would be an improvement over the existing decile-based quality measure benchmark methodology, as the points assigned to the median performance level from the benchmark period would be 10 percent of the MIPS performance threshold, not 6.0 as it is today. A commenter believes that under the decile-based methodology, if most clinicians' scores differ only slightly from each other, then a small difference in a clinician's score could lead to a large penalty. A few commenters also

believe that the proposed methodology, if applied to all quality measures, would encourage clinicians to report more specialty or condition-specific measures and would reduce the complexity and administrative burden clinicians currently face in trying to determine why they received a high or low MIPS quality score as clinicians would be scored by a singular methodology in MIPS. A few commenters did not believe that it is necessary to use a different approach to benchmark non-administrative claims-based measures.

Response: We acknowledge the commenters' recommendation to implement the proposed modified policy for all quality measures in MIPS. In the CY 2017 QPP final rule (81 FR 77286), we finalized that measures submitted by MIPS eligible clinicians are scored using a percentile distribution, separated by decile categories and that for each set of benchmarks, we calculate the decile breaks for measure performance and assign points based on which benchmark decile range the MIPS eligible clinician's measure rate is between. (81 FR 77284).

Based on our analysis of quality measure scores for the CY 2022 performance period/2024 MIPS payment year, we observed substantially lower scores for the administrative claims-based quality measures than for the non-administrative claims-based quality measures. The average quality measure median score for non-administrative claims-based quality measures was above 8 points, while the average quality measure median score for the administrative claims-based quality measures was about 5.5 points. MIPS eligible clinicians who perform near the median performance rate for all MIPS eligible clinicians scored on non-administrative claims-based measure are already receiving scores at or above the performance threshold-derived score. We wanted to ensure that MIPS eligible clinicians who perform near the median performance rate for all MIPS eligible clinicians scored on the administrative claims-based measure would receive scores at, or very close to, the performance threshold-derived score.

The differences in scores between administrative claims-based measures and non-administrative claims based measures, including their medians, led us to propose to modify the methodology for scoring the administrative claims-based measures within the quality performance category beginning with the CY 2025 performance period/2027 MIPS payment year, basing the methodology on standard deviation, median, and an achievement point value that is derived from the performance threshold. Currently, we do not believe that applying the proposed benchmarking methodology to all quality measures is appropriate.

While we do acknowledge the complexity with using different benchmarking policies for administrative claims-based measures and non-administrative claims-based quality measures, we note that clinicians would not need to do anything differently under this new scoring methodology since we automatically score administrative claims-based quality measures using claims data. Additionally, the proposed methodology aligns with the benchmarking methodology used for cost measures, which are also administrative claims-based measures and automatically calculated by CMS. We will continue to monitor the benchmarking methodologies for quality measures to determine if additional proposals are warranted in future years.

Comment: Several commenters suggested that CMS be transparent about how benchmark ranges and standard deviations are set each year, establish specific benchmark range thresholds, determined by standard deviations from the median, in regulation, and solicit formal comments before changing the thresholds. A commenter expressed concern regarding CMS adjusting the ranges to increase the penalties for low scores without adequately assessing the impact of those changes. A commenter requested that CMS provide clear guidance and education to help clinicians understand how their scores are derived under the new methodology and provide frequent and timely feedback to clinicians on their performance throughout the measurement year to allow them time to improve. A commenter recommended that CMS provide additional transparency by publishing illustrative data showing how 2024 performance would have been scored under the proposed benchmarking approach.

Response: We thank the commenters for their recommendations. The methodology for determining the benchmark ranges was described in the CY 2026 PFS proposed rule (90 FR 32760). As proposed, the benchmark ranges, the median, and the performance threshold-derived achievement point values aligned with the median would be dynamic and responsive to changes in performance rates assessed by administrative claims-based quality measures and performance thresholds for each CY performance period/MIPS payment year. Additionally, as performance thresholds are established for each performance period/MIPS payment years, the performance threshold-derived point values could also change. At this time, we review the standard deviations from the median used to determine cutoffs for benchmark ranges for each administrative claims-based quality measure for each year based on measure performance across MIPS eligible clinicians and the performance threshold established for the

performance period/MIPS payment year. We perform analyses when the performance threshold changes to set the benchmark ranges. To determine the benchmark ranges, we adhere to the following principles: (1) the center of performance rates aligns with the performance threshold-derived point value; (2) determination of benchmark ranges according to the statistical distribution curve of the performance rate; and (3) distribution of achievement points for administrative claims-based quality measures in alignment with and within expected ranges seen in the quality performance category overall. Any change to the cutoffs for benchmark ranges is based on performance and the impact of these changes would be analyzed. The benchmark ranges, once available, are posted at https://qpp.cms.gov/benchmarks.

We will continue to monitor the impact of these scoring changes on MIPS eligible clinicians and consider making available additional data. Additionally, we plan to make available additional examples and educational materials to inform MIPS eligible clinicians about the new administrative claim-based quality measure benchmarking methodology modifications and the anticipated impact. We will consider this feedback as we continue to work to improve the quality performance category overall.

Regarding the commenters' requests for frequent and timely feedback for MIPS eligible clinicians on their performance, we currently provide annual MIPS Performance Feedback that includes information on MIPS eligible clinicians' performance for the previous performance period. This feedback typically becomes available during the summer in between the performance period and the MIPS payment year, which is as soon as feasible. We provide these reports on an annual basis, as we calculate administrative claims-based quality measures following the end of the performance period. This is because MIPS administrative claim-based quality measure scores are calculated using benchmarks that are derived from data from all MIPS eligible clinicians, groups, and virtual groups that met the measure's case minimum for that performance period. MIPS eligible clinicians have episodes of care that begin and end at various times throughout the performance period, so to calculate an accurate comparison across clinicians, CMS has historically calculated all scores following the end of the performance period. Calculating the MIPS cost measures during the performance period may provide an incomplete indication of how a MIPS eligible clinician is performing. We are continuing to work towards providing meaningful and timely information on quality measures generally and we recognize the importance of providing this information for measures implemented in MIPS.

Comment: A few commenters suggested that CMS explore the use of prior year data when benchmarking administrative claims-based measures, like used for setting benchmarks for measures derived from EHRs or registries since, unlike cost measures, quality performance does not have "inflation" which would preclude the use of prior year data from setting administrative claims-based quality measure benchmarks.

Response: We appreciate the commenters' suggestions. However, we continue to believe that since administrative claims-based quality measures require no data submission, using performance period benchmarks allows for the calculation of more current and representative measure scores that better track clinician performance and progress over time. While quality performance does not have inflation, we continue to believe that using a performance period benchmark to score these measures, instead of a historical benchmark based on prior year data, allows for measure scores that are more reflective of current performance.

Comment: A commenter requested that CMS monitor for any unintended effects, like reduced score variability or less distinction between high and low performers, and readjust the methodology, if needed. A commenter urged CMS to ensure that the revised methodology does not inadvertently disadvantage small or rural practices with limited patient volume and to monitor the impact of the new scoring approach on measure reliability and clinician engagement. A commenter encouraged CMS to continue refining the benchmarking methodologies to ensure balanced assessments across practice sizes and specialties.

Response: We thank the commenters for their recommendation to monitor the impact of the revised methodology and to readjust, if needed. At this time, our analyses support our intended goal for the proposed modification to the scoring methodology: MIPS eligible clinicians with administrative claims-based quality measure performance near the median for all MIPS eligible clinicians attributed the measure would receive scores at, or very close to, the performance threshold-derived score. We will continue to monitor the impact of these scoring changes on MIPS eligible clinicians on performance, measure reliability, and clinician engagement. We will also monitor the impact of these changes across practice sizes, rurality, and specialties.

After consideration of public comments, we are finalizing our proposals, as proposed, to modify

our scoring methodology for administrative claims-based quality measures beginning with the CY 2025 performance period/2027 MIPS payment year and codify the scoring methodology for administrative claims-based quality measures in the quality performance category at § 414.1380(b)(1)(i) and (b)(1)(ii)(D).

2. MIPS Payment Adjustments

a. Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), CY 2023 PFS final rule (87 FR 70096 through 70102), CY 2024 PFS final rule (88 FR 79373 through 79380), and CY 2025 PFS final rule (89 FR 98448 through 98455).

b. Establishing the Performance Threshold

(1) Statutory Authority and Background

As discussed in this section of this final rule, to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. These special rules are no longer applicable for establishing the performance threshold beginning with the CY 2022 performance period/2024 MIPS payment year. We refer readers to the CY 2024 PFS proposed rule (88 FR 52596) for further information on these previously applicable requirements as they explain our prior computations of the performance threshold.

In the CY 2025 PFS final rule (89 FR 98448 through 98451), we selected the mean as the methodology for determining the performance threshold for the CY 2025 performance period/2027 MIPS payment year through CY 2027 performance period/2029 MIPS payment year. We codified this policy in our regulation at § 414.1405(g)(2), providing that, for each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period as specified at § 414.1405(b)(10) (89 FR 98448 through 98451; 89 FR 98564). In the CY 2025 PFS final rule, we established the performance threshold for the CY 2025 performance period/2027 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data (89 FR 98451 through 98455). We also codified this performance threshold at § 414.1405(b)(10)(i) (89 FR 98451 through 98455; 89 FR 98564).

We note that, in previous years, we have established the performance threshold for each performance period during the rulemaking cycle immediately preceding the performance period. However, section 1848(q)(6)(D)(i) of the Act does not specify when the Secretary shall compute a performance threshold that would apply for each MIPS payment year. Instead, section 1848(q)(6)(D)(i) of the Act provides the Secretary shall compute a performance threshold for each MIPS payment year based on the mean or median (selected once every 3 years) of the MIPS final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. We have determined that the performance threshold may be established with respect to the applicable year at any time as long as the performance threshold continues to be based on a prior period specified by the Secretary. In other words, we could establish a performance threshold that would apply to multiple MIPS payment years. We note

that we may not always establish the performance threshold for multiple MIPS payment years, but we will consider this as an option as we continue to ensure that the performance threshold is truly reflective of MIPS eligible clinicians' performance in MIPS. Due to several large programmatic changes (such as, transitioning to reporting MVPs and digital quality measures and potential introduction of "Core Elements" for selection of quality measures in MVPs) discussed further in sections IV.A.3.b. and IV.A.4.c. of this final rule, establishing the same performance threshold for the 2028, 2029, and 2030 payment years would allow us to provide stability and predictability to MIPS eligible clinicians as they adapt to and implement our policy changes for MIPS.

As further discussed under section IV.B.2.b.(2) of this final rule, we proposed to continue using the mean of the final scores for all MIPS eligible clinicians from the CY 2017 performance period/2019 MIPS payment year to establish the performance threshold as 75 points for the CY 2026 performance period/2028 MIPS payment year through the CY 2028 performance period/2030 MIPS payment year. We recognized that our proposal to establish the performance threshold for MIPS payment years 2028, 2029, and 2030 extends beyond the period for which we have established the mean methodology to determine the performance threshold. However, given the current statutory requirement, which allows us to reassess the methodology every 3 years, there is no requirement that prevents us from setting the methodology for a longer time frame. We plan to reassess the methodology in future rulemaking.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), CY 2023 PFS final rule (87 FR 70096 through 70100), CY 2024 PFS final rule (88 FR 79373 through 79380), and CY 2025 PFS final rule (89 FR 98448 through 98455).

We codified the performance thresholds for each of the first 9 years of MIPS at § 414.1405(b)(4) through (10). These performance thresholds are shown in Table C-J1.

TABLE C-J1: PERFORMANCE THRESHOLDS FOR THE CY 2017 PERFORMANCE PERIOD/2019 MIPS PAYMENT YEAR THROUGH THE CY 2025 PERFORMANCE PERIOD/ 2027 MIPS PAYMENT YEARS

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period	2024 MIPS Performance Period	2025 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 points	75 points	75 points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points	0 points	0 points

(2) Performance Threshold for the CY 2026 Performance Period/2028 MIPS Payment Year through the CY 2028 Performance Period/2030 MIPS Payment Year

In the CY 2026 PFS proposed rule, we proposed to use the mean of 75 points from the CY 2017 performance period/2019 MIPS payment year as it continues to be the most appropriate for establishing the performance threshold for the 2028, 2029, and 2030 MIPS payment years for several reasons (90 FR 32763 through 32765). As further described in this section of this final rule, these reasons include providing stability and predictability for MIPS eligible clinicians, allowing MIPS eligible clinicians to gain experience with MVPs and other new MIPS policies, and continuing to support solo, small, and rural practices.

TABLE CJ-2: POSSIBLE VALUES FOR THE PERFORMANCE THRESHOLD FOR THE 2028, 2029, AND 2030 MIPS PAYMENT YEARS

MIPS Payment Years	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	2024 MIPS Payment Year	2025 MIPS Payment Year
Mean	74.65	87.00	85.65	89.47	89.22	82.71	83.18

At the time of the CY 2026 proposed rule, we had data available on MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year through CY 2023 performance period/2025 MIPS payment year. As shown in Table C-J2, we calculated the mean values of MIPS eligible clinicians' final scores for each year from the CY 2017 performance period/2019 MIPS payment year through the CY 2023 performance period/2025 MIPS payment year. As discussed in the

CY 2026 proposed rule, we did not have MIPS eligible clinicians' final scores available from the CY 2024 performance period/2026 MIPS payment year and, therefore, the mean final score for the CY 2024 performance period/2026 MIPS payment year was not included for consideration as a potential performance threshold value for the 2028, 2029, and 2030 MIPS payment years. As discussed further in this section of this final rule, we believe that the mean of 75 points from the CY 2017 performance period/CY 2019 MIPS payment year continues to be the most appropriate option that would provide stability and predictability for MIPS eligible clinicians while still encouraging high quality of care.

First, when looking at the data for purposes of establishing a performance threshold for the 2028 through 2030 MIPS payment years, we did not consider any data from the CY 2019 performance period/2021 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year, as they were impacted by the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID-19), which we discussed in further detail in the CY 2025 PFS final rule (89 FR 98451 through 98453). The geographic differences of COVID–19 incidence rates along with different impacts resulting from Federal, State, and local laws and policy changes implemented in response to the PHE for COVID–19 may have affected which MIPS eligible clinicians were able to submit data for the CY 2019 performance period. This may have led to final scores that were not wholly representative of performance for all MIPS eligible clinicians. Also, for the CY 2020 performance period/2022 MIPS payment year and the CY 2021 performance period/2023 MIPS payment year, we extensively applied our reweighting policies, described at § 414.1380(c)(2)(i), to MIPS eligible clinicians nationwide due to the PHE for COVID-19.

Inherently, these actions, particularly re-weighting the performance categories, skewed the final scores from those years such that they are not an appropriate indicator for future performance of MIPS eligible clinicians. Specifically, we are concerned that the final scores during the PHE for COVID-19 reflect the performance of only MIPS eligible clinicians that may have been less impacted by the pandemic, and do not accurately represent MIPS eligible clinician performance overall during this period. Since the Federal PHE for COVID-19 expired on May 11, 2023,[469] many of the flexibilities and exceptions applied during the PHE for COVID-19, such as the extreme and uncontrollable circumstances reweighting policies described at § 414.1380(c)(2)(i), are no longer being applied in the context of the

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[469] https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.

pandemic. In the interest of establishing a performance threshold using data that is reflective of clinician performance that is not affected by the-PHE for COVID-19, continuing to use data from the CY 2017 performance period/2019 MIPS payment year to establish a performance threshold for the 2028, 2029 and 2030 MIPS payment years will allow us time to gather additional data that is more reflective of clinician performance outside of the PHE for COVID-19. We acknowledge more recent data will be available between CY 2026 performance period/2028 MIPS payment year through CY 2028 performance period/2030 MIPS payment year; however, with the various programmatic changes discussed in this section of the proposed rule, we aim to provide stability and predictability to MIPS eligible clinicians as they transition, implement, and adapt to these changes.

As new MVPs and their related changes are being introduced into the program, and as more MIPS eligible clinicians transition to MVP reporting, we want to provide some stability for MIPS eligible clinicians and allow time for more MVP data to become available. Specifically, in section IV.A.3. of this final rule, we discuss several policies to support our goal of phasing out traditional MIPS and fully transitioning to MVP reporting. As stated in the CY 2025 PFS proposed rule, we discussed that we anticipate to fully transition to MVPs by the CY 2029 performance period/2031 MIPS payment year (89 FR 62012). In section IV.A.3.b. of this final rule, we solicited comments in an RFI for a potential policy wherein MVP Participants would select one quality measure from a subset of quality measures in each MVP, referred to as "Core Elements" and MVP Participants would select the other 3 required quality measures and would still have to meet existing MVP reporting requirements. We are considering proposing the Core Elements policy in the CY 2027 PFS proposed rule and proposing the policy for implementation prior to sunsetting traditional MIPS. Further, as discussed in section IV.A.4.c. of this final rule, we aim to fully transition to a digital quality measure (dQM) landscape that promotes interoperability and increases the value of reporting quality measure data. As we continue to consider these potential policy changes over the next several years, we aim to provide consistency to MIPS eligible clinicians by maintaining the performance threshold at 75 points for the 2028, 2029, and 2030 MIPS payment years. Meanwhile, we will continue to evaluate how the performance threshold can best reflect clinicians' performance in MIPS.

While the CY 2018 performance period/2020 MIPS payment year's data predate the PHE for COVID-19, we continue to be concerned that an increase in the performance threshold will inadvertently harm certain clinician types, specifically small practices and solo practitioners. As we stated in the CY 2024 PFS final rule, we want to consider the impacts of the performance threshold and its related policies on small practices (88 FR 79377). As discussed in the CY 2025 PFS final rule, we have received feedback that many small practices and solo practitioners face challenges in their ability to participate in MIPS, including the costs to implement and maintain certified electronic health record (EHR) technology (CEHRT), staff and training costs, and limited staff capacity to manage the complexity of the program (89 FR 98451 through 98453). As discussed in the CY 2025 PFS final rule, we also learned that increases in the performance threshold add administrative and financial burden for small practices that discourage their participation in MIPS (89 FR 98451 through 98454).

Further, in a survey distributed during the summer of CY 2024, we learned that, of the small practices and solo practitioners that participated in the survey, the three major barriers for submitting MIPS data included: the burden of data collection and submission, lack of administrative support, and high costs associated with participating in the program. The small practices and solo practitioners that responded to the survey indicated that simplified reporting requirements, free technical assistance, and better informational resources may improve their participation in MIPS.

Though we have several policies within MIPS that continue to support small and solo practices, including scoring and reweighting policies, we are interested in understanding how to best support small practices and enhance their ability to successfully participate in MIPS as MIPS continues to evolve (89 FR 98451 through 98453). As such, we continue to perform qualitative analysis through engagement with small practices, third party intermediaries, and other interested parties to gather information about the experience of small practices participating in the program. Maintaining a performance threshold of 75 points for the 2028, 2029, and 2030 MIPS payment years would allow us to continue developing strategies to reduce barriers for small practices and solo practitioners participating in MIPS.

Finally, as discussed in section IV.B.1.a.(2) of this final rule, we are continuing to assess how to best address our topped-out scoring policy within the quality performance category. Historically, there have been concerns that certain specialties only have topped out measures to report, which would make it

difficult for them to meet an increased performance threshold even if they perform very well on those measures. Hence, as we continue to evaluate these programs scoring policies, establishing the performance threshold at 75 points will avoid inadvertently harming these clinician types.

Alternatively, in the CY 2026 PFS proposed rule (90 FR 32765), we considered maintaining the performance threshold at 75 points for either: (1) the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year (excluding the CY 2028 performance period/2030 MIPS payment year, which is currently proposed); or (2) only the CY 2026 performance period/2028 MIPS payment year. We also considered raising the performance threshold. However, as previously discussed, based on the data that we have available, we believe that our proposal to set the performance threshold at 75 points for the 2028, 2029, and 2030 payment years provides stability as MIPS enters a period of transition agnostic of our discretion to reassess the performance threshold methodology for the CY 2028 performance period/2030 MIPS payment year. We will reassess the use of the median or mean methodology in future rulemaking in accordance with section 1848(q)(6)(D)(i) of the Act. We refer readers to section IV.B.2.b.(3) of this final rule for Request for Information (RFI) on Future MIPS Performance Thresholds for more discussion on establishing the performance threshold for single versus multiple years and potentially increasing the performance threshold in future rulemaking.

We refer readers to the section VII.I.5.d.(4)(c) of this final rule for an estimate of the percent of MIPS eligible clinicians that would receive a negative payment adjustment for the CY 2026 performance period/2028 MIPS payment year if the performance threshold is set at 75 points as proposed.

Maintaining a performance threshold of 75 points allows additional time for more MVP data to become available, continues to provide opportunities for clinicians to become familiar with the transition to MVPs, and ensures that we continue to support certain clinician types, such as small practices, solo practitioners, rural providers, and clinicians who have several topped out measures. Therefore, we proposed to establish a performance threshold of 75 points for the 2028, 2029, and 2030 MIPS payment years based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year. We also proposed to codify this performance threshold by adding § 414.1405(b)(10)(ii).

We solicited public comments on our proposal to establish a performance threshold of 75 points

for the 2028, 2029, and 2030 MIPS payment years based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year. We also solicited comments on our proposal to codify this performance threshold by adding § 414.1405(b)(10)(ii).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to continue using the mean of 75 points from CY 2017 performance period/2019 MIPS payment year for the CY 2026 performance period/2028 MIPS payment year. Many commenters agreed that this proposal would provide stability and predictability for clinicians as they transition to MVPs and adjust to the cost performance category changes. Some suggested that it would also alleviate the burden on smaller practices as they do not have adequate resources to meet an increased performance threshold. A few commenters shared their belief that this would help alleviate the burden on physicians as they deal with inflation. At least one commenter appreciated the stability as they work on developing additional quality measures for their specialty.

Response: We thank the commenters for their support.

Comment: A commenter stated that they do not support the performance threshold of 75 for the CY 2026 through 2028 performance periods/CY 2028 through 2030 MIPS payment years due to concerns that the CY 2017 performance/2019 MIPS payment year data being used to establish the mean is too old. More specifically, the comment stated that MIPS participation in 2017 was significantly lower than today and using data from the CY 2017 performance/2019 MIPS payment year is not necessarily reflective of the program today.

Response: We thank the commenter for their feedback. We acknowledge that we want to utilize the data that is most reflective of MIPS eligible clinicians' performance for the purpose of establishing the performance threshold. However, as noted, for the 2028 through 2030 MIPS payment years, we did not consider any data from the CY 2019 performance period/2021 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year, as they were impacted by the PHE for COVID-19 and related policies. Additionally, while we have CY 2018 performance period/2020 MIPS payment year data available which predates the PHE for COVID-19, we note that the mean of the performance period data from that time would be 87 points and we continue to be concerned that an increase in the performance

threshold will inadvertently harm certain clinician types, specifically small practices and solo practitioners. Hence, in the interest of establishing a performance threshold using data that is reflective of clinician performance that is not affected by the-PHE for COVID-19, we continue to use data from the CY 2017 performance period/2019 MIPS payment year to establish a performance threshold for the 2028, 2029 and 2030 MIPS payment years. This will also allow time to continue to gather additional data that is more reflective of clinician performance outside of the PHE for COVID-19.

Comment: A commenter supported the proposal to continue using the mean of 75 points from CY 2017 performance period/2019 MIPS payment year for the CY 2026 performance period/2028 MIPS payment year but expressed concerns with small and rural practices and how they continue find it challenging to meet the performance threshold compared to larger group practices.

Response: We have several policies within MIPS that continue to support small and rural practices, including bonus points (83 FR 59847 through 59850) and reweighting policies (86 FR 65521 through 65524), and opportunities to apply for hardships (81 FR 77240 through 77243). As we continue to conduct related analysis, we will continue to consider the impact of the performance threshold on small and rural practices.

Comment: A commenter expressed concerns that it was not within statutory limitations to establish the performance threshold for multiple years.

Response: We disagree. Section 1848(q)(6)(D)(i) of the Act provides the Secretary shall compute a performance threshold for each MIPS payment year based on the mean or median of the MIPS final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. We have determined that the performance threshold may be established with respect to the applicable year at any time if the performance threshold continues to be based on a prior period specified by the Secretary.

After consideration of public comments, we are finalizing as proposed to establish a performance threshold of 75 points for the 2028, 2029, and 2030 MIPS payment years based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year. We are also finalizing our proposal to codify this performance threshold by adding § 414.1405(b)(10)(ii).

(3) Request for Information on Future MIPS Performance Thresholds

As we consider the potential changes within MIPS while aiming to ensure that the performance

threshold reflects clinician performance, we also requested public feedback on the following issues:

- Establishing the performance threshold for single versus multiple years (for example, 1, 2, or 3 years at a time) via rulemaking; and
- As we approach later years in MIPS, increasing the performance threshold based on data from a prior period which potentially would provide larger positive MIPS payment adjustments for MIPS eligible clinicians with MIPS final scores higher than such performance threshold.

We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

c. Example of Adjustment Factors

Figure C-J1 provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2026 performance period/2028 MIPS payment year. In Figure C-J1, the performance threshold is set at 75 points, as we have proposed in section IV.B.2.b.(2) of this final rule.

For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2026 performance period/2028 MIPS payment year. We calculate the MIPS payment adjustment factor using a linear sliding scale in accordance with section 1848(q)(6)(F)(i) of the Act. This linear sliding scale is calculated based on MIPS final scores from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment.

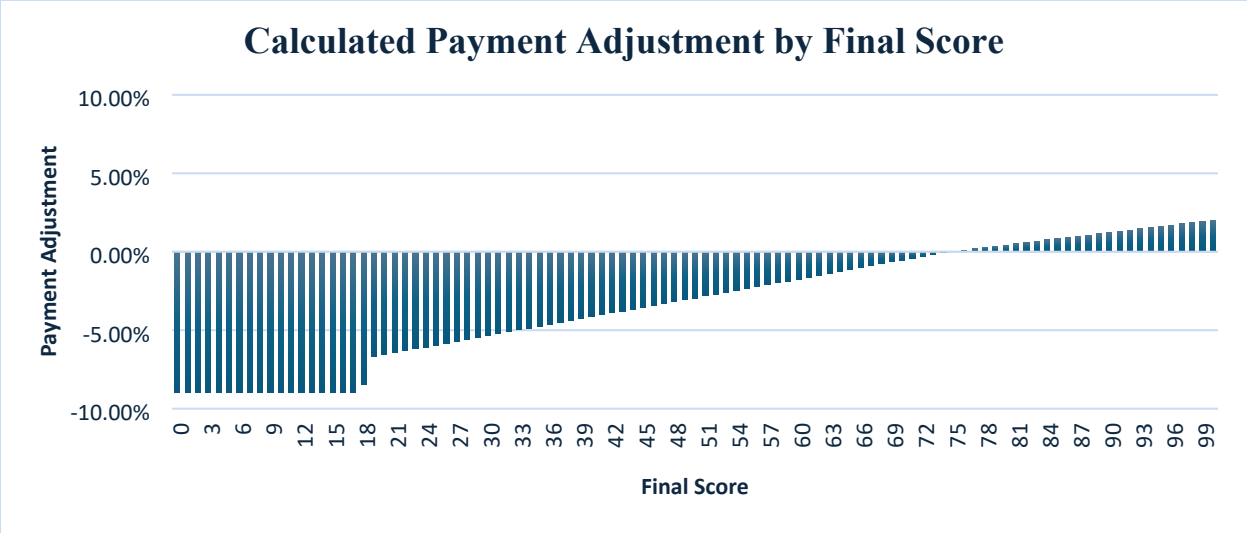
However, there are two modifications to this linear sliding scale. First, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the proposed performance threshold of 75 points for the CY 2026 performance period/2028 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor

is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent (the applicable percentage). If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 75 points (the performance threshold proposed for the CY 2026 performance period/2028 MIPS payment year) will receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 5 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE C-J1: ILLUSTRATIVE EXAMPLE OF MIPS PAYMENT ADJUSTMENT FACTORS BASED ON FINAL SCORES AND PERFORMANCE THRESHOLD FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table C-J3 illustrates the changes in payment adjustment based on the final policies from the CY 2025 PFS final rule (89 FR 98448 through 98455) for the CY 2025 performance period/2027 MIPS

payment year and the finalized policies for the CY 2026 performance period/2028 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE C-J3: ILLUSTRATION OF POINT SYSTEM AND ASSOCIATED ADJUSTMENTS COMPARISON BETWEEN THE CY 2025 PERFORMANCE PERIOD/2027 MIPS PAYMENT YEAR AND THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

2025 Performance Period Final Score Points	MIPS Adjustment for 2025 Performance Period	2026 Performance Period Final Score Points	MIPS Adjustment for 2026 Performance Period
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.00	0% adjustment	75.00	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

3. Review and Correction of MIPS Final Score – Feedback and Information to Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are required to provide MIPS eligible clinicians with timely confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule, we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories (82 FR 53799 through 53801).

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; for the CY 2021 performance period/2023 MIPS payment year on

August 22, 2022; for the CY 2022 performance period/2024 MIPS payment year on August 10, 2023; for the CY 2023 performance period/2025 MIPS payment year on August 12, 2024, and for the CY 2024 performance period/2026 MIPS payment year on September 9, 2025 We direct readers to *qpp.cms.gov* for more information.

4. Third Party Intermediaries General Requirements

a. Requirements for CMS-approved Survey Vendors

(1) Background

The CAHPS for MIPS survey evaluates patients' experiences of care within a group, subgroup, virtual group, or Alternative Payment Model (APM) Entity. The CAHPS for MIPS survey must be administered by a CMS-approved survey vendor for the purposes of reporting (81 FR 28285). CMS-approved survey vendors must undergo the CMS approval process annually, which includes completing the Vendor Participation Form and complying with the Minimum Survey Vendor Business Requirements (81 FR 28288).

We have codified definitions of key terms for the Quality Payment Program, including third party intermediaries such as CMS-approved survey vendors, at § 414.1305. First, we have defined a third-party intermediary as meaning an entity that CMS has approved at § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. Then, we also defined a CMS-approved survey vendor as meaning a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and to transmit survey measures data to CMS.

We refer readers to § 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77386), the CY 2018 Quality Payment Program final rule (82 FR 53818 and 53819), the CY 2019 PFS final rule (83 FR 59907 and 59908), the CY 2022 PFS final rule (86 FR 65538 and 65539), and the CY 2025 PFS final rule (89 FR 98459 and 98460) for previously finalized standards and criteria for third party intermediaries including CMS-approved survey vendors.

(2) Codification of Two Previously Finalized Policies

In the CY 2025 PFS final rule, we finalized a policy to require CMS-approved survey vendors to submit a range of the cost of their services with their application beginning with the CY 2026 performance period/2028 MIPS payment year (89 FR 98459 and 98460). While this policy was finalized as proposed in the CY 2025 PFS final rule, it was not codified in regulations governing third party intermediaries. To ensure program requirements are clear, in the CY 2026 PFS proposed rule, we

proposed to codify this previously finalized policy at § 414.1400(d)(9), with a technical modification to indicate that this requirement begins on January 1, 2026, rather than with the CY 2026 performance period/2028 MIPS payment year (90 FR 32768). We specifically proposed to codify at § 414.1400(d)(9) to provide that, beginning with January 1, 2026, the entity seeking to be a CMS-approved survey vendor must include on its application the range of costs of its third-party intermediary services (90 FR 32768).

In the CY 2024 PFS final rule, we finalized a policy to require organizations to contract with a CMS-approved survey vendor that would administer the CAHPS for MIPS Survey in the Spanish language translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines (88 FR 79332 through 79334). While this policy was finalized as proposed in the CY 2024 PFS final rule, it was not codified in regulations governing third party intermediaries. To ensure program requirements are clear, we proposed to codify this previously finalized provision at § 414.1400(d)(3)(iv)(A), with technical modifications to refer more broadly to sub-regulatory guidance that details procedures for administering the CAHPS for MIPS Survey. Specifically, we proposed to codify at § 414.1400(d)(3)(iv)(A) to provide that, beginning on January 1, 2024, in addition to administering the survey in English, entities will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in sub-regulatory guidance to standardize the CAHPS data collection process for MIPS and to make sure the survey data collected across survey vendors are comparable within the program or model (90 FR 32768).

We received public comments on these proposals to codify at § 414.1400(d)(9) to provide that, beginning with January 1, 2026, the entity seeking to be a CMS-approved survey vendor must include on its application the range of costs of its third party intermediary services and to codify at § 414.1400(d)(3)(iv)(A) to provide that, beginning on January 1, 2024, in addition to administering the survey in English, entities will administer the Spanish survey translation to Spanish-preferring patients. The following is a summary of the comments we received and our responses.

Comment: A few commenters noted their support for codifying CMS' previously finalized policy to require an entity to administer the CAHPS for MIPS Survey Spanish translation to Spanish-preferring patients.

Response: We thank commenters for their support.

Comment: A few commenters noted their support for codifying CMS' previously finalized proposal to require CMS-approved survey vendors to submit a range of the cost of their services with their application.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing as proposed to codify at § 414.1400(d)(9) to provide that, beginning with January 1, 2026, the entity seeking to be a CMS-approved survey vendor must include on its application the range of costs of its third party intermediary services and to codify at § 414.1400(d)(3)(iv)(A) to provide that, beginning on January 1, 2024, in addition to administering the survey in English, entities must administer the Spanish survey translation to Spanish-preferring patients.

(3) Technical Changes

While reviewing the regulations for CMS-approved survey vendors, we identified an area in which language was used to describe survey protocols that is no longer consistent with current practice. In the CY 2026 PFS proposed rule (90 FR 32768) we proposed to modify § 414.1400(d)(3)(i) by removing the reference to 'mixed -modes' to better align with language typically used in current practice. Specifically, we proposed to modify § 414.1400(d)(3)(i) to provide that an entity must have at least 3 years of experience administering surveys in which mail survey administration is followed by survey administration via Computer Assisted Telephone Interview (CATI) (90 FR 32768). We noted that this terminology change does not reflect a change in requirements for CMS-approved survey vendors.

We solicited public comments on this proposal to make a technical change to the regulation text at § 414.1400(d)(3)(i).

We did not receive public comments on this provision, and therefore, we are finalizing the technical change to the regulation text at § 414.1400(d)(3)(i) as proposed.

(4) CAHPS for MIPS Survey

For the MIPS quality performance category, the CAHPS for MIPS Survey measures patients' experience of care and is administered first through the mail and then by phone interview with non-respondents. The survey is administered in English and Spanish, with additional translations available. The CAHPS for MIPS Survey may only be administered by CMS-approved survey vendors. (81 FR

77116). More details on the CAHPS for MIPS survey can be found here: https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/cahps-mips.

(5) Requirement for Web-Mail-Phone Protocol for Administration of the CAHPS for MIPS Survey

In the CY 2025 PFS proposed rule (89 FR 61869, 62042, and 62043), we included a request for information (RFI) on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. We solicited public comments on this new protocol given positive results found from our 2023 CAHPS for MIPS Web Mode Field Test. [470]

The field test added the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration, and we found that the addition resulted in a 43 percent response rate compared to 28 percent for the mail-phone protocol from the CY 2022 performance period CAHPS for MIPS Survey (89 FR 62043). In the CY 2025 proposed rule, we outlined details of the field test, including that surveys were administered to a random sample of survey-eligible patients from 20 Medicare Shared Savings Program ACOs between March 6, 2023, and May 31, 2023. These results were compared to survey data collected from the CY 2022 performance period CAHPS for MIPS Survey for the same Medicare Shared Savings Program ACOs.

Although comments in response to the RFI were not included in the 2025 PFS final rule, commenters widely supported an expansion of CAHPS for MIPS survey modes to include a web-based survey protocol, emphasizing that this could help increase response rates. A commenter noted that this is a long overdue update. The CAHPS for MIPS Survey RFI received input from 16 commenters, including medical societies, professional trade associations, Accountable Care Organizations, health care systems, an academic/research institution, and a consumer/patient advocacy organization. Key commenter takeaways included encouraging CMS to:

- Expand the CAHPS for MIPS survey modes to include a web-based option.
- Examine and implement additional changes to improve response rates and reduce burden associated with CAHPS surveys.

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[470] Centers for Medicare & Medicaid Services. (June 2024). 2023 CAHPS for MIPS Web Mode Field Test. Available at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2893/2023_CAHPS_for_MIPS_WebMode_Field_Test.pdf.

● Create additional approaches to assess and reduce any increased costs of survey administration for health care practices.

● Consider the potential impacts of sharing email addresses with vendors on patient privacy and administration burden.

The field test showed an increase in the survey response rate due to the addition of the web-based survey protocol which may lead to more groups meeting case minimum requirements for CAHPS. Additionally, adding a web survey mode increased flexibility for survey respondents, and commenters responded positively to the addition of a web-based survey protocol.

On these bases, in the CY 2026 PFS proposed rule we proposed to require that, beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. We propose to codify this requirement at § 414.1400(d)(10) (90 FR 32678 through 32769).

In addition, we proposed to codify new requirements at §§ 414.1400(d)(3)(v)(A), 414.1400(d)(3)(vi)(A), and 414.1400(d)(3)(vii) to ensure an entity applying to become a CMS-approved survey vendor is capable of administering a web-mail-phone protocol prior to CMS approval (90 FR 32769). We noted that, currently, an entity must apply to be a CMS-approved vendor on an annual basis, demonstrating they meet applicable requirements at § 414.1400. We proposed to modify our requirements at § 414.1400(d)(3) to ensure an entity is prepared to administer the web-mail-phone protocol prior to CMS approval. Specifically, we proposed that, beginning January 1, 2027, to be a CMS-approved survey vendor an entity must have sufficient experience, capability, and capacity to accurately report CAHPS data by demonstrating that they (1) use equipment, software, computer programs, systems, and facilities that can send survey invitations via email that include a patient-specific hyperlink to a web survey, collect data via web, and track cases from web surveys through telephone follow-up activities (§ 414.1400(d)(3)(v)(A)); (2) employ a web survey administrator (§ 414.1400(d)(3)(vi)(A)); and (3) have at least 3 years of experience administering surveys in which web survey administration is followed by survey administration via mail survey or Computer Assisted Telephone Interview (CATI) (§ 414.1400(d)(3)(vii)) (90 FR 32769).

As finalized, CMS will update the survey administration requirements and associated materials, including the survey vendor application, during the 1-year implementation delay. We note that entities seeking to, or that do, become a CMS-approved survey vendor would need to meet other applicable requirements at § 414.1400, including successfully completing CMS' vendor training(s) as provided at § 414.1400(d)(5).

We refer readers to section V.B.5.b. of this final rule for discussion on the burden estimates for this proposal.

We received public comments on this proposal to require that, beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted their support for CMS' proposal to require that CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. Many commenters stated their belief that this policy will have positive impacts from the increased survey response rates. Specifically, commenters shared their beliefs that this policy would: allow more patient voices to be heard; improve the quality and usefulness of the survey; modernize patient engagement; allow physician practices the flexibility to administer the survey in the best possible manner for their patients; and reduce burden on patients. A commenter also encouraged CMS to preserve this multimode design as it modernizes CAHPS survey administration to preserve accessibility, particularly for beneficiaries who may have limited internet access or digital literacy.

Response: We thank commenters for their support.

Comment: A commenter believes that to further enhance accessibility and response rates, CMS should consider adding Short Message Service (SMS) text messaging as an additional modality for survey administration.

Response: We thank the commenter for the response, and we will take this suggestion into consideration if we plan to include additional survey modes in future years. We note that any future additional requirements for the administration of the CAHPS for MIPS Survey will be proposed and finalized through future rulemaking.

Comment: A few commenters expressed their concern that the proposed policy will increase the cost of administering the survey. A commenter urged CMS to assess and disclose the cost implications for medical practices, noting their belief that implementing a three mode protocol may introduce new financial and operational burdens, particularly for small and rural practices. This commenter also stated their belief that CMS should cover the costs of survey administration to avoid shifting financial responsibility onto physician practices.

A few commenters expressed concern about the burden for clinicians. Specifically, a commenter recommended that CMS ensure this policy is implemented in a way that minimizes burden for clinicians and survey vendors. Another commenter encouraged CMS to refine the various CAHPS surveys to remove duplication across programs and reduce burden for clinicians.

Response: We recognize the commenter's concern about the potential for additional cost burden of the web-mail-phone protocol to organizations fielding the CAHPS for MIPS survey, though CMS does not estimate the costs associated with a MIPS eligible clinician's vendor support. We believe any additional costs incurred by the web-mail-phone protocol are outweighed by the potential benefits, as field tests found that the addition of the web mode resulted in a 43 percent response rate compared to 28 percent for the mail-phone protocol from the CY 2022 performance period CAHPS for MIPS Survey (89 FR 62043). The initial field test demonstrates that adding the web mode promotes better response rates by enabling more patients to participate in the survey and increasing flexibility for practices and survey respondents. We also note that we do not consider requiring CAHPS survey administration across programs to be duplicative. Collecting CAHPS survey data for different quality programs ensures that patient experience data is collected across the services and appropriate for the care measured by each program. The surveys focus on matters that patients report are important to them and for they are the best and/or only source of information. It is our goal to capture this data across care settings (for example, hospitals, clinics, long-term care).

Comment: A few commenters believe that the web administration of the CAHPS for MIPS survey should remain optional. A commenter stated their belief that practices should have the ability to determine what survey mode (that is, web, phone, or mail) is most appropriate for their patient population.

Response: The addition of web administration will provide another option for survey respondents

to participate in the CAHPS for MIPS Survey. We are prioritizing this flexibility in participation options for survey respondents as initial field tests indicate that our proposed policy to require CMS-approved survey vendors to administer the survey via a web-mail-phone protocol may increase participation in the survey to survey respondents. The 2023 CAHPS for MIPS Web Mode Field Test showed a 15-percentage point increase in the survey response rate due to the addition of the web-based survey protocol, indicating that a subset of patients prefer the web mode. We believe that patients should be given the opportunity to choose their preference between web, phone, or mail response options.

Comment: A commenter expressed concern that clinicians have difficulty obtaining a sufficient number of survey responses to ensure reliability and validity. This commenter urged CMS to continue to monitor and address this issue, particularly as survey modalities evolve. The commenter also urged CMS to avoid requiring practices to provide patient email addresses.

Response: We note that, as discussed previously in this section of the final rule, the 2023 CAHPS for MIPS Web Mode Field Test added the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration, and found that the addition resulted in a 43 percent response rate compared to 28 percent for the mail-phone protocol from the CY 2022 performance period CAHPS for MIPS Survey (89 FR 62043). As such, we believe that adding the web-based survey mode will increase response rates, which may lead to more groups meeting case minimum requirements for CAHPS and strengthen the reliability and validity of the CAHPS for MIPS Survey measure. Additionally, electing to share patient email addresses with CMS-approved survey vendors is one action a practice can, but is not required to take to promote survey participation and response, just like sharing patient phone numbers or preferred language.

After consideration of public comments, we are finalizing our proposal to require that, beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors would have to administer the CAHPS for MIPS Survey via a web-mail-phone protocol and to codify this requirement at § 414.1400(d)(10) as proposed.

(6) Sunsetting Application Requirement at § 414.1400(d)(8)

In the CY 2026 PFS proposed rule, we proposed to modify § 414.1400(d)(8) to sunset its requirement that, to apply to become a CMS-approved survey vendor, the entity must send an interim

survey data file to CMS that establishes the entity's ability to accurately report CAHPS data (90 FR 32769). Though this requirement was established to ensure accurate reporting, it is ultimately not feasible to implement because an entity cannot collect data until it is approved by CMS, and thus, the entity does not have any data to send to CMS prior to approval. Therefore, submission of a survey data file has not been used as a requirement for approval. We proposed to sunset the requirement at § 414.1400(d)(8) so it is only effective from January 1, 2019 (when it was first finalized in the CY 2019 PFS final rule) through December 31, 2025. We proposed that this requirement would no longer be in effect beginning January 1, 2026.

We did not receive public comments on this provision, and therefore, we are finalizing our proposal to sunset the requirement at § 414.1400(d)(8) as proposed.

5. Advanced APMs

a. Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. Our vision for increased clinician participation in Advanced APMs is aimed at integrating individuals' clinical needs across a spectrum of providers and settings to improve patient care and population health. As we continue to make improvements to the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs.

In the CY 2025 PFS final rule (89 FR 98463 and 98464), we anticipated that we would propose a comprehensive approach to QP determination in future rulemaking (89 FR 98464). In the CY 2026 PFS proposed rule (90 FR 32593 through 32597), we proposed such a comprehensive approach, which includes two parts. First, we proposed adding an individual level calculation to Qualifying APM Participant (QP) determinations, as set forth in proposed § 414.1425(b)(3 and (c)(3), for all eligible clinicians participating in an Advanced APM, such that each eligible clinician would receive both APM Entity level calculation and an individual level calculation. Second, we re-proposed to expand the scope of the services in the sixth criterion of the definition of "attribution-eligible beneficiary" at § 414.1305 to use covered professional services (section 1848(k)(3)(A) of the Act). In the proposed rule we explained that CMS expected that , together, these proposals would modernize and improve the QP determination approach across Advanced APMs.

In addition to the previous proposals, we further proposed to sunset our Advanced APM criterion at § 414.1415(c)(7), which currently limits Medical Home Model participants to 50 clinicians.

Lastly, we proposed modifying § 414.1455(a)(b)(3)(ii) and (b)(3)(vi) pertaining to the QP Targeted Review process to align with MIPS Targeted Review process set forth at § 414.1385 to ensure that the QP and MIPS Targeted Reviews occur concurrently.

b. QP Determinations

(1) General

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy for QP determinations at § 414.1425. Currently, § 414.1425(b)(1) provides that, for the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the "snapshot dates" (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any such snapshot date is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for eligible clinicians in an APM Entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List for more than one APM Entity, but who do not achieve QP status based on any APM Entity-level determinations, we make QP determinations at the individual level as described at § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual-level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described at § 414.1425(b)(2).

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77440) we established a process to calculate Partial QP status at § 414.1425(d). While to date our Partial QP policies have impacted only a small number of eligible clinicians, and thus we have not focused our discussion on this specific policy, we note that any changes to QP determinations at § 414.1425 also would likely require conforming changes to the policies for Partial QPs for consistency across the program.

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457), we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is

based on numbers of patients. Both methods use the ratio of "Attributed beneficiaries" to "Attribution-eligible beneficiaries," as these terms are defined at § 414.1305, as shown in Figure CN1.

FIGURE CN1: QP DETERMINATION CALCULATION

$$\frac{\text{Attributed beneficiaries}}{\text{Attribution-eligible beneficiaries}}$$

Regulation at § 414.1435(d) provide that if the Threshold Score (using either the payment amount or patient count method) calculated at the APM Entity or individual eligible clinician level, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinician or clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) achieve QP status for such year.

Regulation at § 414.1435(b)(3) provides that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) provides that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period are excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be attribution-eligible beneficiaries because the QP performance period does not align with the Advanced APM's performance period or attribution period, or for other reasons. There may also be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. As described in the CY 2017 Quality Payment Program final rule (81 FR 77451), attributed beneficiaries are a subset of attribution-eligible beneficiaries. Therefore, when calculating Threshold Scores for QP

determinations, we exclude from the list of attributed beneficiaries any beneficiaries who do not meet the criteria to be attribution-eligible beneficiaries at that point in time.

(2) Individual QP Determination

When we initially established our policy in the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445) to make most QP determinations at the APM Entity level, we believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for an APM Entity between the goal for its eligible clinicians to achieve QP status under the Quality Payment Program and the goals of the Advanced APM(s) in which the APM Entity participates.

In the CY 2024 proposed rule (88 FR 52618), we proposed to address this issue by conducting all QP determinations at the individual level. However, commenters opposed that proposal, citing issues such as administrative burden for APM Entities tracking QP status and Partial QP status and elections at the individual level because of the implications for MIPS reporting. Many further believed that the change may have negative consequences for specialists, the opposite of our intent in making our proposal. In light of the comments received, we did not finalize our proposal from the CY 2024 proposed rule (88 FR 79403). Since that time, we have continued to examine QP determinations with a desire to right-size the methodology to current and future Advanced APM design, remove barriers to participation, and conduct calculations fairly.

Some commenters on our CY 2024 proposal recommended that we conduct QP determinations at both the APM Entity and individual levels (88 FR 79403). At the time, we indicated that we did not believe that this approach would sufficiently encourage more intensive Advanced APM participation by individual eligible clinicians. However, based on continued examination of QP determinations, including in the time since the publishing of the CY 2025 PFS final rule, we have recognized the importance of individual contribution, particularly for models that are condition-specific or focused on an episode of care. Clinicians in these models are particularly disadvantaged when, as is frequently the case, their APM Entity fails to achieve QP status.

Under our current policy, there is the potential that an eligible clinician who has fully engaged with an Advanced APM may still be unable to earn QP status because it is calculated at the APM Entity level as described at § 414.1425(c)(3). As we previously noted, under our current policy we conduct

individual determinations, but we only do so in the following specific circumstances: (1) for eligible clinicians who appear on a Participation List for more than one APM Entity, but who do not to achieve QP status based on any APM Entity-level determinations, we make QP determinations at the individual level as described at § 414.1425(c)(4), (2) for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual-level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described at § 414.1425(b)(2). While these methods exist, individual calculations are not the norm, and for an eligible clinician in only one APM Entity our current policy does not provide for an individual determination.

As such, we proposed adding a new provision at § 414.1425(b)(3) to add a QP determination at the individual level for all Advanced APM participants, beginning with the 2026 QP Performance Period. As we explained in the CY 2026 proposed rule (90 FR 32593), this proposal would not impact our policy at § 414.1425(b)(1) for APM Entity -level determinations or our policy at § 414.1425(b)(2) determinations for Affiliated Practitioners as these policies also would remain in effect for 2026 and future QP Performance Periods. We proposed amending at § 414.1425(b)(3) to add a calculation of Threshold Scores for QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM based on services furnished across all Tax Identification Numbers (TINs) to which the eligible clinician has reassigned their billing rights. This individual Threshold Score would provide a more specific measurement of each eligible clinician's participation in an Advanced APM. We proposed that we would calculate at the APM Entity-level as provided at § 414.1425(b)(1) and (2) and the individual level for each eligible clinician as provided at § 414.1425(b)(3) at each of the snapshot dates throughout the QP Performance Period. We also proposed that, an eligible clinician is a QP for a year under the Medicare option if, as described at § 414.1435(d), they meet or exceed the QP payment amount threshold or QP patient count threshold, as described at § 414.1430(a)(1) and (3), for that QP Performance Period, at the APM Entity-level, or as an individual eligible clinician as stated at § 414.1425(c)(3) or (c)(4) respectively.

We proposed to amend § 414.1425(c)(3) by adding a new (c)(3)(ii) and making conforming revisions at § 414.1425(c)(3)(i) and (4) to ensure that an eligible clinician is a QP for a year under the

Medicare Option if beginning with the CY 2026 QP Performance Period, the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described at § 414.1430(a)(1) and (3). Likewise, an eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described at § 414.1430(b)(1) and (3).

We proposed a conforming revision to sunset at § 414.1425(c)(4) to clarify that the existing policy started with the CY 2017 QP Performance Period and would end with the CY 2025 QP Performance Period, and to preserve in the regulations the history of the applicable policies for specific QP Performance Periods.

We proposed a revision at § 414.1425(d)(1) and (2) such that an eligible clinician is a partial QP for a year under the Medicare option if they meet or exceed the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described at § 414.1430(a)(2) and (4) at the APM Entity-level or as an individual eligible clinician as stated at §§ 414.1425(d)(1) or (d)(2) respectively. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to add an individual-level QP determination beginning in the 2026 QP Performance Period. These commenters emphasized that the inclusion reflects clinician engagement and ensures fairness across specialties and noted that this change would prevent clinicians from being disadvantaged when their APM Entity does not meet thresholds.

Response: We agree with commentors that adding an individual-level QP determination will improve fairness, particularly for specialists and clinicians in condition-specific or episode-based models. This policy will help to ensure that individual contributions to Advanced APMs are recognized, even when the APM Entity does not, as a whole, achieve QP status.

Comment: Some commenters cautioned that implementing individual-level QP determinations could increase administrative complexity. The commenters expressed concern that tracking QP status and

Partial QP status at the individual level across multiple snapshots throughout the QP performance period would add a burdensome process.

Response: We appreciate the comments and recognize that this policy will increase the number of clinicians and organizations tracking individual calculations. We are committed to aligning our QP determination process as much as is practicable with existing QPP reporting requirements. As such, in part to minimize the burden of tracking QP status at multiple points within the QP performance period, we will be providing individual QP determination calculations for all three snapshots when we deliver the third snapshot feedback at the end of the QP performance period. That way, rather than needing to track individual QP status throughout the QP performance period, clinicians can simply check when the third snapshot feedback is released and receive their final individual QP determination result. This operational approach is consistent with how we have delivered individual QP determination feedback in the specialized situations under which we currently perform individual-level QP determinations. Moreover, in waiting to perform the individual-level calculations until after the third snapshot, we are able to take into account any APM Entities that were terminated from their Advanced APM participation after the first, second, or third snapshot, which is an action that can result in the loss of previously attained QP status at § 414.1425(c)(5) and (6) and could result in the eligible clinician being subject to MIPS. Rather than recalculate individual determinations based on such terminations, which both are inefficient operationally and have potential to confuse eligible clinicians and cause them to misunderstand their MIPS obligations, we can perform calculations for all three QP snapshot periods based on the most up-to-date participation as of the third snapshot and provide only the final answer to the relevant clinicians. Because this approach simply continues how we already perform and release both APM Entity-level and individual-level QP calculations, clinicians and practice representatives will be able to continue engaging with QPP as they always have, with APM Entity-level determinations being performed and released at each snapshot and individual-level determinations being performed and released at the third snapshot. We believe this approach will continue to maximize efficiency and transparency and reduce confusion for and administrative burden on eligible clinicians. We will continue to monitor and provide updates regarding the QP determination process where we believe there are necessary improvements.

After consideration of public comments, we are finalizing our policy to add an individual QP determination for all eligible clinicians as proposed.

(3) Attribution-eligible Definition

At § 414.1305, we define an attribution-eligible beneficiary as a beneficiary who--

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base beneficiary attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and other services.

When we finalized the definition of attribution-eligible beneficiary in the CY 2017 Quality Payment Program final rule, (81 FR 77451 through 77452), we intended that this definition would, for purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define attribution-eligible beneficiary were aligned with the attribution methodologies and rules for our contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. We chose to refer to E/M services as the primary basis for purposes of attribution-eligibility because many of the Advanced APMs CMS offered at that time used E/M claims to attribute beneficiaries to their APM Entity groups. Over time, we have updated the list of services that are considered to be E/M services for purposes of identifying attribution-eligible beneficiaries and have published this list as part of

the "2024 Learning Resources for QP Status and APM Incentive Payment" materials on the Quality Payment Program Resource Library at *qpp*.cms.gov.

We also included an exception in this sixth criterion to allow us to use an alternative approach for Advanced APMs that do not base beneficiary attribution on any E/M services, and thus for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for an E/M service. To date, we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two-Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify attribution-eligible beneficiaries for these Advanced APMs in the "2024 Learning Resources for QP Status and APM Incentive Payment" materials on the Quality Payment Program Resource Library at *qpp.cms.gov*.

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which beneficiary attribution is based on services other than E/M services, the attributed beneficiary population is truly a subset of the Advanced APMs' attribution-eligible beneficiary populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations would be appropriate for such Advanced APMs. That said, our thought when we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. We believed that, by affording sufficient flexibility within the program, we could both foster innovation in Advanced APMs and simplify our execution of the program. However, with our more narrowly defined default approach to beneficiary attribution (relying on claims for E/M services), we have increasingly needed to exercise the flexibility to identify an alternative approach to attribution eligibility for Advanced APMs that fell into the exception, which meant that we identified several individually tailored ways of performing the beneficiary attribution methodology for specific Advanced APMs. We anticipate that Advanced APMs will continue to evolve and use novel

approaches to value-based care that may emphasize a broad range of covered professional services, and in that event the application of our current regulations may result in increased variability among the ways we define attribution-eligible beneficiary when making QP determinations. In the CY 2025 PFS proposed rule (89 FR 62098 through 62101), we proposed to amend the final criterion in the definition of "attribution-eligible beneficiary" at § 414.1305 to expand the scope of services used to covered professional services, indicating that we would conduct further analysis. However, as further discussed in the CY 2025 PFS final rule (89 FR 98461 through 98465), we did not finalize this proposal.

After continued examination, in the CY 2026 PFS proposed rule, we re-proposed to modify the sixth criterion of the definition of "attribution-eligible beneficiary" at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician for whom we are making the QP determination, beginning with the 2026 QP Performance Period. In the CY2026 PFS proposed rule, we referred to the description of this proposed approach that CMS previously provided in the CY 2025 proposed rule, namely, that this policy, if finalized, would result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflect eligible clinicians' actual participation in Advanced APMs, improve transparency and predictability of the determinations, be more operationally efficient than the current policy, and better align the QP determination methodology with the universe of services to which the Quality Payment Program (including MIPS and APMs) applies.

In response to comments in the CY 2025 PFS final rule, we explained that changes in the composition of APM Entity Participation Lists, services furnished, and attributed beneficiaries all have significant effects on the number of projected versus actual QPs for a QP performance period, which complicates the ability to assess effects of methodological changes to QP determinations (89 FR 98461 through 98465). We also described how any methodology changes can lead to varied QP Threshold Scores for APM Entities within the same Advanced APM, and noted that because QP status is determined based on specific QP payment amount and QP patient count thresholds, only those changes in scores that result in an eligible clinician crossing over a QP threshold percentage contribute to the net estimated change in QP counts (89 FR 98461 through 98465). In the CY 2026 PFS proposed rule, we also noted that the QP thresholds have increased relative to previous years and, effective with the 2025 QP

Performance Period are now at 75 percent for the payment amount and 50 percent for the patient count. We noted that this change, which occurs by statute, will be responsible for the largest quantitative effect on our QP predictions, largely by reducing the number of QPs relative to the previous, lower thresholds. As such, while the quantitative effects of our proposals may show small changes in the number of QPs relative to the status quo, that status quo itself reflects this threshold level change to QP determinations, which is significant in its own right.

In the CY 2025 PFS final rule (89 FR 98463 and 98464), we stated that we believed that our proposal was a better approach than the status quo, and we believed that it should likely be part of a comprehensive approach to QP determinations that would better reflect the current and future state of Advanced APMs. In response to public comments, we did not finalize at that time the proposal to revise the sixth criterion of the definition of "attribution-eligible beneficiary at § 414.1305. However, at the time we stated that we anticipated to propose a comprehensive approach to QP determination in future rulemaking, including a strategy to address the needs of condition-specific models, and that this proposal might be included as one element of such future proposals (89 FR 98463 and 98464). We have further explored this issue and have determined that we could appropriately address the challenges we have described in this and prior rulemaking by allowing for the overall expansion of the QP determinations, in terms of both the level of determination as discussed in section XX.XX.x.(2). of this final rule, and the services included in the QP determinations as discussed in this section of the rule.

As we previously noted in this final rule, in our discussion of the proposal to calculate QP status at the individual NPI level, primary care practitioners generally furnish a higher proportion of E/M services than do specialists with the same beneficiary, and as for the Threshold Score calculations described previously, the emphasis on E/M services in our beneficiary attribution policy may have inadvertently encouraged APM Entities to exclude specialists from their Participation Lists. Under our current policy, if one or more eligible clinicians on the APM Entity's Participation List furnish covered professional services to a beneficiary but none of those services are among the E/M services we use for attribution, that beneficiary would not be attribution-eligible, and therefore, would not be included in our QP determination calculation, even though the beneficiary is actually receiving covered professional services from an eligible clinician on the APM Entity's Participation List.

We proposed to change the definition of "attribution-eligible beneficiary" at § 414.1305 so that, beginning with QP Performance Period 2026, a single definition using covered professional services would be applied regardless of the Advanced APMs in which the eligible clinician participates. As we explained in the CY 2026 proposed rule, we believed that this complements our proposal to add individual-level calculations to QP determinations. We were also concerned that retention of the current policy where E/M services are the default basis for attribution, and where special processes are required for Advanced APMs that use a different attribution basis, could result in a complex set of unique attribution approaches for Advanced APMs.

We believe that this change would more appropriately recognize the Advanced APM participation of the eligible clinicians for whom these determinations are being made, particularly when considered in conjunction with the proposal to add an individual-level calculation to QP determinations. We further believe that this proposal would simplify and streamline QP determinations and address the challenges to Advanced APM participation reportedly faced by specialists who are less likely than primary care practitioners to provide E/M services.

We proposed to modify the sixth criterion in the definition of "attribution-eligible beneficiary" at § 414.1305 to provide that, beginning with the 2026 QP Performance Period, an attribution-eligible beneficiary is a beneficiary who during the QP Performance Period has a minimum of one claim for any covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity at any determination date during the QP Performance Period.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of the CMS proposal to include Covered Professional Services in the QP determination method where it provides opportunities for participants, specifically clinicians who are less likely to provide E/M services, to receive credit for providing services to an attributed beneficiary.

Response: We appreciate the supportive comments and note that, while we have observed that factors outside our control such as the statutory QP thresholds and the eligible clinician makeup of a specific APM Entity have significant effects on QP determination results, we expect that for certain

Advanced APMs, such as the Kidney Care Choices Model, the Enhancing Oncology Model (EOM), and the Transforming Episode Accountability Model (TEAM), this policy change may increase the number of QPs relative to the number there would have been in the absence of this change.

Comment: A few commenters not only supported the proposal but further suggested that CMS implement the proposed policy retroactively for the 2025 QP Performance Period rather than waiting until 2026.

Response: We appreciate these comments. However, it is not operationally feasible to build the process change timely to perform it for the 2025 QP performance period. The QP determinations for the majority of the year have been performed already, and there is insufficient time to develop and incorporate updates to the QP determination formula, test them for accuracy, perform the updated determinations, and communicate the results timely for clinicians who would have to report to MIPS in 2026 for MIPS Performance Period 2025 to prepare for such reporting.

Comment: Several commenters expressed concern that the impact of switching the scope of services used in QP determinations on Advanced APM participants was unknown, especially where participants have consistently received calculations that use E/M services. Several such commenters were opposed to the CMS proposal to switch from E/M to Covered Professional Services in the QP determination method as they believed that this proposed change would lower the APM Entity score for certain ACO participants. A few such commentors suggested that we modify our proposal to provide a calculation at the APM Entity level using E/M services and the individual QP determination calculation using Covered Professional Services.

Response: We appreciate the concern and note that the impact of this policy is unlikely to be uniform across all Advanced APMs, or even across APM Entities or individual eligible clinicians within a single Advanced APM. In our proposal, we noted that we expect few APM Entities to notice a significant difference between their results using E/M services and Covered Professional Services. In fact, for ACOs specifically, we expect that for some, the APM Entity-level score will be higher based on Covered Professional Services, and for others, their score could decrease. We note that regardless of the direction of a change in scores, the impact bears meaning only when the change results in crossing a QP or Partial QP threshold percentage; for example, under current thresholds, if the proposed policy would result in an

ACO's payment amount score increasing from 48 percent to 51 percent, that would cross the 50 percent Partial QP threshold and therefore attain Partial QP status for that ACO, which would be more meaningful than a situation where an ACO's payment amount score changed from 35 percent to 45 percent. However, we recognize that our estimates represent only point-in-time examples of the effects of our proposed policy, not consistent or predictable long-term effects, because QP determination results are influenced by several mutable factors outside the parameters of the determination formula, as we described in more detail in a response to comment as part of the CY 2025 Physician Fee Schedule final rule (89 FR 98463). In that same response, we further noted that a change in score affects the net estimated counts of QPs and Partial QPs only when a QP or Partial QP threshold score is crossed. This is true irrespective of magnitude; a patient count score change from 50 percent to 70 percent has no effect (this NPI would be a QP either way) on the total estimate, but a patient count score change from 48 percent to 52 percent does (this NPI would go from Partial QP to QP due to the score change). As such, our practice has been to use quantitative analyses principally to assess the potential range or general magnitude of a change in QP calculations, and to look for consistency with our general expectations or the presence of any surprising results. We continue to believe that identifying a single methodology across all Advanced APMs may offer certain benefits related to consistency and transparency across the Advanced APM program, and we remain committed to ensuring that our policies support participation in Advanced APMs. Therefore, we believe the concerns expressed by commenters around unintended consequences for some Advanced APM participants warrant our modifying our proposal. Specifically, we are finalizing a modified version of our proposed policy, namely by maintaining the calculation of QP determinations using E/M services under both the patient count and payment amount methodologies and by also adopting our proposed policy to calculate QP determinations using Covered Professional Services, also for both the patient count and payment amount methodologies. Because this modification in effect creates two versions of each calculation, we are effectuating this final policy by amending § 414.1435 to create, effective with the 2026 QP Performance Period, separate calculations that use E/M services and Covered Professional Services, respectively. We further are finalizing amendments at § 414.1305 to support and clearly delineate these separate calculations by establishing two separate definitions for attribution-eligible beneficiaries—both a "Covered Professional Service attribution-eligible

beneficiary" and an "E/M attribution-eligible beneficiary," each corresponding with the appropriate set of serviced described in the amendments to § 414.1435. To provide determination methods using both definitions, we are adopting a modified version of our proposed policy to include amendments at § 414.1435(c) and (d) that provide, starting with the 2026 QP performance period, for a determination first for the Covered Professional Service methods (payment and patient count), and at § 414.1435(e) and (f) for the E/M methods (payment and patient count). We appreciate commenters' suggestions to use E/M for APM Entity-level calculations and Covered Professional Services for individual-level calculations. However, we believe that using both sets of services across both the patient count and payment amount methods and at both the APM Entity and individual levels, and then using the highest score, will give us the opportunity to compare the methodologies over time without risking that a choice between the two sets of services has unintentionally and unfairly disadvantages any participants. This change to the proposal to use both the existing E/M services approach and the proposed Covered Professional Services approach will give us the opportunity to monitor the effects of each approach, particularly the use of E/M services in our QP determination methodology, to ensure that our methodology reflects and rewards meaningful participation in Advanced APMs. The use of the highest score is consistent with our existing approach to QP determinations at § 414.1435(h) (§ 414.1435(d) prior to the effective date of this final rule) where we use the higher of the patient count and payment amount scores and with our approach to use the higher of the APM Entity-based and individual clinician scores. We also believe it is fair given that different commenters have different concerns with each respective approach; while we are learning how scores compare across Advanced APM designs, specialties, etc., no Advanced APM participants are being disadvantaged in scoring outcomes. We note that the design and operation of Advanced APMs is expected to continue to evolve over time—particularly for CMS Innovation Center models which are inherently designed to continue innovating on contemporaneous baseline delivery and payment systems—and that, as always, we will continue to monitor the effects of each the existing and the new approaches to QP determinations with a plan to revisit our methodology if and when we determine that a future change is warranted. We remind our readers that some of the challenges that led us to the policies we are finalizing in this final rule were identified and shared with us by Advanced APM participants, and we continue to want to hear about the impacts of our policies on participants' experiences in their Advanced

APMs.

After consideration of public comments, we are finalizing with modification our policy at §§ 414.1435 and 414.1305 to perform QP determinations using both an E/M services approach and a Covered Professional Services approach.

c. Medical Home Model 50 Eligible Clinician Limit

In the CY 2017 Quality Payment Program final rule (81 FR 77428), we finalized a policy for the Medical Home Model nominal financial risk criterion to set a limit of 50 on the number of eligible clinicians in an organization that participates as an Advanced APM through a Medical Home Model. In the CY 2023 PFS final rule (87 FR 70117), we amended § 414.1415(c)(7) to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity.

Likewise, in the CY 2017 Quality Payment Program final rule (81 FR 77468) we finalized a policy at § 414.1420(d)(2) and (4) for the Medicaid Medical Home Model nominal financial risk criterion to set a limit of 50 on the number of eligible clinicians in an organization that participates as an Advanced APM through a Medical Home Model. In the CY 2020 PFS final rule (84 FR 63095) we finalized a proposed amendment at § 414.1420(d)(2) and (4) to include Aligned Other Payer Medical Home Models with the existing Medicaid Medical Home Model financial risk and nominal amount standards for Medicaid Medical Home Models.

When we established the medical home model 50 eligible clinician limit in the CY 2017 Quality Payment Program final rule our stated intent was to encourage organizations capable of taking on significant downside risk to participate in Advanced Alternative Payment Models that met the "Generally applicable financial risk standard" at § 414.1415(c)(1) (81 FR 77430). Based on our experience operating the Quality Payment Program we note that participation in Advanced APMs has increased, and the necessity of the Medical Home Model 50 eligible clinician limit has lessened. Moreover, we expect that this policy could provide a barrier for participation in models that meet the Medical Home Model definition in the future.

We proposed to amend the policy at § 414.1415(c)(7) to provide that beginning with the 2026 QP Performance Period we will no longer apply the Medical Home Model 50 eligible clinician limit.

Specifically, we proposed to modify § 414.1415(c)(7) to sunset that provision and provide that it only applies from the 2023 QP performance Period through the 2025 QP Performance Period.

Additionally, we proposed a conforming amendment to the Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit at § 414.1420(d)(8) beginning in the 2026 performance period we will no longer apply the Medical Home Model 50 eligible clinician limit.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed their concern that the CMS proposal to no longer apply the Medical Home Model 50 eligible clinicians limit may limit participation in Advanced APMs by eligible clinicians in rural areas and those at small practices.

Response: We appreciate the commenters' desire to provide opportunities for small and rural practices. We do not anticipate that this change will have any impact on eligible clinicians in rural areas or to those with small practices. The proposed policy would not bar their participation in a Medical Home Model nor would it require an Advanced APM to allow larger participants; it simply would allow a Medical Home Model to operate without needing to examine the size of participants.

Comment: Many commenters expressed their support for the CMS proposal to no longer apply the Medical Home Model 50 eligible clinician limit.

Response: We appreciate the support to sunset the 50-clinician limit for Medical Home Model participants.

After consideration of public comments, we are finalizing this policy as proposed.

d. Targeted Review of QP Determinations

In the CY 2021 PFS final rule (85 FR 84952), we finalized a policy to provide an opportunity for eligible clinicians to bring to our attention potential clerical errors we may have made that could have resulted in the omission of an eligible clinician from a Participation List used for purposes of QP determinations, and for us to review and make corrections if warranted. We also finalized that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period (85 FR 84952). We noted that, consistent with section 1833(z)(4) of the Act, and as provided at § 414.1455(a), there is no

right to administrative or judicial review at sections 1869 or 1878 of the Act, or otherwise, of the determination that an eligible clinician is a QP or Partial QP at § 414.1425, or of the determination of the amount of the APM Incentive Payment at § 414.1450.

In the CY 2021 PFS final rule (85 FR 84953), we finalized our proposal to align the timing and procedures for this targeted review process with the MIPS targeted review process as codified at § 414.1385. We noted this alignment would reduce the likelihood of confusion and burden on eligible clinicians and APM Entities. In the CY 2024 PFS proposed rule (88 FR 79380 through 79382 and 88 FR 79408), we modified the Targeted Review period for both MIPS and QPs such that we could meet our statutory obligation to apply the differentially higher QP conversion factor beginning on January 1 of each payment year beginning with CY 2026. When we made these updates, we also revised the language at § 414.1385 more generally, including a change from 30 days to 15 days between notification and a response at § 414.1385(a)(5), but we did not make corresponding changes to the QP Targeted Review at § 414.1455.

We recognized that the different language in the current versions of these two sections of regulation could make it appear that our intent is for the MIPS and QP Targeted Review periods to operate differently, and that in fact the inconsistencies could mean that the Targeted Review for both QPs and MIPS participants is not guaranteed to be aligned. Our intent for these Targeted Review periods to be aligned has not changed, and we do not want to give the impression that there is a misalignment between them. Accordingly, we proposed to modify the langauge at § 414.1455(b)(3)(ii) and (b)(3)(vi) to make clear that the same timing requirements that for MIPS Targeted Reviews that are currently specified in at § 414.1385(a)(2) and (a)(5) also apply for purposes of QP Targeted Reviews.

We solicited comments on our proposal to modify the language at § 414.1455(b)(3)(ii) and (b)(3)(vi) to the same timing requirements as that of MIPS Targeted Reviews specified at § 414.1385(a)(2) and (a)(5). The following is a summary of the comments we received and our responses.

Comment: A few commentors expressed concern that the CMS proposal would shorten the duration of the Targeted Review period for QPs and may not provide enough time to submit a Targeted Review.

Response: We appreciate the comments and agree that it is important to provide a sufficient window to submit a Targeted Review. However, we note that our proposed amendment to the regulatory text would not change anything about how the current Targeted Review period actually operates. We recognize that it was not clear that the QP and MIPS Targeted Reviews operate together as part of a single QPP experience, and our proposal was simply to clarify by aligning the language of the two regulatory sections.

Comment: Many commentors expressed support for the CMS proposal to modify the language at § 414.1455(b)(3)(ii) and (b)(3)(vi) to the same timing requirements as that of MIPS Targeted Reviews specified at § 414.1385(a)(2) and (a)(5).

Response: We appreciate the commenters' support for our proposal.

After consideration of public comments, we are finalizing this policy as proposed.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq*.), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a "collection of information" requirement (as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations) is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2026 PFS proposed rule (90 FR 32352), we solicited public comments on each of the aforementioned issues for the following sections of this document that contained information collection requirements (ICRs). Comments received are summarized under each relevant section.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/2024/may/oes_nat.htm). In this regard, Tables D-A1 and D-A2 present BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We note that the May 2024 BLS data does not include median hourly wage rates for multiple physician occupation types listed in Table D-A2; in these cases, the BLS identifies that the median wage rate is equal to or greater than $115.00/hr or $239,200 per year. BLS data for prior years, such as the

May 2022 and May 2023 data, provide similar notes for median wage rates for occupations that are above the same thresholds ($115.00/hr or $239,200 per year for the May 2022 BLS data (https://www.bls.gov/oes/2022/may/oes_nat.htm) and May 2023 BLS data (https://www.bls.gov/oes/2023/may/oes_nat.htm)). Therefore, for consistency with previous years for estimating physician wage rates, we have continued to use mean hourly wage rates across our wage estimates.

TABLE D-A1: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	23.80	23.80	47.60
Business Operations Specialists	13-1000	43.76	43.76	87.52
Computer System Analysts	15-1211	53.83	53.83	107.66
General and Operations Managers	11-1021	64.00	64.00	128.00
Licensed Practical and Licensed Vocational Nurses	29-2061	30.84	30.84	61.68
Medical and Health Services Managers	11-9111	66.22	66.22	132.44
Secretary/Administrative Assistant	43-6000	22.90	22.90	45.80
Software Quality Assurance Analysts and Testers	15-1253	53.01	53.01	106.02
Training and Development Managers	11-3131	67.59	67.59	135.18
Chief Executive Officer	11-1011	126.41	126.41	252.82

For our purposes, BLS' May 2024 National Occupational Employment and Wage Estimates do not provide an occupation that we could use for "Physician" wage data. To estimate a Physician's costs, we used an average conglomerate wage of $299.32/hr as demonstrated below in Table D-A 2.

TABLE D-A2: National Occupational Employment and Wage Estimates (Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Anesthesiologists	29-1211	161.85	161.85	323.70
Family Medicine Physicians	29-1215	123.47	123.47	246.94
General Internal Medicine Physicians	29-1216	126.31	126.31	252.62
Obstetricians and Gynecologists	29-1218	135.16	135.16	270.32
Orthopedic Surgeons, Except Pediatric	29-1242	175.51	175.51	351.02
Pediatric Surgeons	29-1243	216.74	216.74	433.48
Pediatricians, General	29-1221	106.89	106.89	213.78
Physicians, All Other	29-1229	121.86	121.86	243.72
Psychiatrists	29-1223	129.39	129.39	258.78
Surgeons	29-1240	170.56	170.56	341.12
Surgeons, All Other	29-1249	178.50	178.50	357.00
Total				3,292.48
Average Physician Wage (3,292.48/11)				299.32

B. Information Collection Requirements (ICRs)

1. Ambulatory Specialty Model (42 CFR Part 512 and section III.C of this final rule)

In section III.C of this final rule, we discuss testing the Ambulatory Specialty Model and finalized provisions for the model under the authority of the Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing, evaluation, and expansion of models under section 1115A of the Act. As a result, the information collection requirements contained in this rule are not subject to the requirements of the PRA. However, the anticipated impact is scored below in section VII.I.5. of the Regulatory Impact Analysis.

We did not receive public comments related to the information collection requirements related to ASM, and therefore, we are finalizing provisions as discussed in section III.C of this final rule.

2. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program (§§ 410.79, 414.84, and 424.205)

In section § 410.79(b), we are finalizing our proposal to make changes to regulation Conditions of Coverage. First, we are finalizing our proposal to amend § 410.79(b) by revising the definitions of

"Extended flexibilities period" and "Online" and adding definitions for three new terms for MDPP, including "Live Coach interaction," "Online delivery period," and "Online session." The definitions will extend virtual delivery flexibilities through December 31, 2029, describe accepted delivery modes for MDPP, and further align MDPP terminology with CDC DPRP Standards[471]. These finalized changes to the definitions aim to remove access barriers for beneficiaries and provide suppliers with more delivery options in response to comments regarding the increasing demand for virtual participation options.

We are finalizing our proposal to amend § 410.79(c)(1)(ii) by clarifying that weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the completion of the MDPP session. After consideration of public comments indicating that the proposed 2 day timeframe was overly restrictive, we are finalizing the changes to the provision at § 410.79 (c)(1)(ii) to allow for weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record with an updated timeframe of five (5) calendar days, which provides sufficient flexibility while maintaining clear separation between sessions. Additionally, we are finalizing our proposal to amend § 410.79(e)(3)(iii)(C) to revise weight collection requirements for MDPP in response to comments regarding increased flexibility for MDPP participants who may be traveling or unable to obtain weight measurements at home due to mobility and safety considerations. This change allows beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site while maintaining program integrity through existing date-stamp requirements described at § 410.79(e)(3)(iii)(c) which state that the photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scaled on the date associated with the billable MDPP session.

Finally, we are finalizing our proposal to amend § 410.79 by adding paragraph (f) to test the addition of coverage of an asynchronous, Online delivery modality during the "Online delivery period" (until December 31, 2029), and clarify that MDPP suppliers are not required to maintain in-person delivery capability during the Online delivery period. These changes will allow virtual-only organizations

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[471] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.

to enroll in Medicare as MDPP suppliers, streamline the process to allow for greater delivery of Online sessions, and promote alignment with the 2024 CDC DPRP Standards.

Upon further review of existing regulations, CMS has determined that current requirements for make-up sessions do not adequately address Online delivery. Make-up sessions for Online delivery were referenced in the CY 2026 PFS proposed rule at § 410.79 (f)(2)(i)(C), which states the Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component) or fully asynchronously (that is, Online). Therefore, CMS is finalizing additional updates to ensure regulatory clarity for make-up sessions offered through Online delivery by revising existing requirements at § 410.79(d)(1), which state "an MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person or distance learning delivery." CMS is revising this language to indicate that Online delivery is also an accepted delivery modality for make-up sessions by specifically stating that "an MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person, distance learning, or Online delivery." CMS would like to reiterate that the Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component) or fully asynchronously (that is, Online). Therefore, a supplier may not offer an Online make up session to a beneficiary who is participating in MDPP through In-person, Distance learning, or In-person with a distance learning component delivery.

We are finalizing the proposed edits throughout § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text to update language to include all accepted MDPP delivery modes for performance goals in which beneficiaries achieve weight loss milestones and adding paragraph (c)(3) to indicate payment for Online delivery, including the inclusion of a new Healthcare Common Procedure Coding System (HCPCS) G-code for online delivery. Finally, we are finalizing the proposed changes to redesignate paragraphs (c)(3) and (4) as paragraphs (c)(4) and (5) respectively and revise the redesignated paragraph (c)(4)(ii) to include a payment rate for a core session or core maintenance session furnished Online during the Online delivery period.

Lastly, we are finalizing our proposal to amend § 424.205(c)(10) to allow the minimum number of required MDPP core sessions and core maintenance sessions to be delivered Online during the Online delivery period; § 424.205(f)(2)(i) to include the online modality among acceptable session types for session documentation; and § 424.205(f)(5) to update requirements for achieving 5 and 9 percent weight loss measured in accordance with § 410.79(c)(ii). Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions, including the collection of weights.

We did not receive public comments on the ICRs for MDPP, and therefore, we are finalizing these changes as proposed.

3. ICR Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act (IRA)

Section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, we shall exclude from the total number of units for a Part D rebatable drug, for an applicable period, those units for which a manufacturer provides a discount under the 340B Program. In association with the CY 2026 Physician Fee Schedule Proposed rule, we solicited comments on a new information collection request to enable us to collect information to implement this voluntary reporting. The following proposed changes will be submitted to OMB for review under control number 0938-1485 (CMS-10930).

In section III.I. of this final rule, we are finalizing the proposed policies to establish a 340B repository and allow 340B covered entities (hereinafter "covered entities") to optionally begin submitting to the 340B repository data elements from 340B identified claims for covered Part D drugs billed to Medicare Part D. We will allow covered entities to begin submitting the fields specified by CMS to the 340B repository beginning in 2026 for Part D 340B-identified claims with dates of service on or after January 1, 2026. This testing period will provide data for us to conduct usability testing for the 340B repository and allow covered entities to develop and test processes for submitting data elements to the 340B repository. We will not use the data submitted for user testing to remove units from Part D inflation rebates unless and until a policy to do so is proposed and finalized. Please see section III.I. of this final rule for detailed information on these policies.

We proposed that covered entities may voluntarily submit data directly to us (or a contractor) to be included in the 340B repository. We will consider all five data elements received by the 340B repository to be associated with 340B Part D claims; that is, we (or a contractor) will not further verify the 340B status of a claim but rather, the 340B repository will serve solely to store these data. Under this process, we will require a certification from covered entities that choose to submit data to the 340B repository that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B-identified claims for the covered entity at the time of submission for dates of service during the relevant period.

We established in the final rule that covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 will submit the fields specified by us on a quarterly basis to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. We established that covered entities that choose to submit data will report data elements related to all 340B Part D claims with dates of service on or after January 1, 2026. We will provide a deadline that we believe would be necessary to allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. We will provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate ICR is approved. During the rest of the testing period, we anticipate that covered entities will be expected to report data on a quarterly basis to the 340B repository within 3 months of the end of a given calendar quarter. We understand that covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B eligibility of claims using data provided by covered entities and their contract pharmacies. We will allow covered entities that choose to participate, to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. Covered entities would certify and would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf. The data from these quarterly submissions would be used to assess the usability of such data to remove 340B units from the total number of units and total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c),

respectively. We established that covered entities participating in the 340B repository during the testing period beginning in 2026 provide information identifying the covered entity, specifically the covered entity's 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS), when submitting claim information to the 340B repository. We will use the collected identifying information to (1) perform analyses to assess suitability of the data for future use in removing 340B units, and (2) provide a means to follow up with the covered entity on questions related to claims data submission.

In the proposed rule, we estimated that approximately 6,500 covered entities will respond and submit data to the 340B Repository Data Elements Reporting Form for CY 2026 based on internal CMS analyses of the unique 340B ID numbers in the HRSA OPAIS database that are active (that is, not terminated) with at least one contract pharmacy association listed and based on comments received on the CY 2025 PFS proposed rule from interested parties, including covered entities, requesting and expressing support for the establishment of a 340B repository.

Using the wage rates from Table 74 of the proposed rule, we expect, for a covered entity or its TPA, a dedicated Software Quality Assurance Analyst and Tester, or team of analysts, 6 hours sampling for each submission and a General and Operations Manager 2 hours reviewing each submission.

In aggregate, we estimated an annual burden of 208,000 hours (6,500 covered entities or TPAs x 8 hr/response x 4 responses/year) at a cost of $23,195,120 (26,000 responses x [(2 hr x $128.00/hr) + (6 hr x $106.02/hr)]).

TABLE D-A3: SUMMARY OF TOTAL ANNUAL BURDEN FOR ALL COVERED ENTITIES OR TPAS TO COMPLETE 340B REPOSITORY DATA ELEMENTS REPORTING FORM IN 2026

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act	0938-1485 (CMS-10930)	6,500 Covered Entities or TPAs	26,000 (6,500 x 4 submissions per year)	8	208,000	Varies	23,195,120

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported CMS establishing the proposed voluntary 340B repository in calendar year 2026. A commenter emphasized that covered entities are facing new requirements and challenges and stated that the proposed testing period is critical to assess CMS' and providers' investment of time and resources into reporting to the repository.

By contrast, many other commenters requested that CMS make reporting to the repository mandatory for covered entities and their contractors. A few of these commenters stated that without a mandatory requirement, the repository will not fulfill the legal requirement to remove 340B units. Some commenters stated that a mandatory repository would provide a more comprehensive and accurate method for identifying and excluding 340B units than a voluntary repository. A commenter recommended that if CMS does not implement a requirement to submit to the repository initially, it should make submission mandatory for key types of large hospitals such as DSH and Rural Referral Centers (RRCs), stating that these hospitals have sophisticated software to manage their 340B programs which could streamline submission to the repository. A few commenters requested that CMS clarify that the repository will be mandatory in 2027, which they state could encourage covered entities to use the repository when it is voluntary in 2026. A couple of commenters stated under the inflation rebate invoicing timeline, CMS could establish and test a repository and require covered entities to retrospectively report 340B claim data for 2026 to the repository once it is operational.

Some commenters expressed concern that with voluntary reporting, the repository is unlikely to receive submissions from a significant number of covered entities. One of these commenters stated that time, system set up, and an attestation requirement reduce incentives for covered entities to submit data to a voluntary repository. Another commenter stated that covered entities have consistently opposed efforts to increase transparency in the 340B Program through broader access to claims data. A few commenters stated that low submission rates could impede CMS' ability to acquire the necessary data to test the repository. Another commenter stated that hospitals have had poor compliance rates with CMS-mandated price transparency reporting and, therefore, the commenter has little confidence that voluntary reporting to the repository would meet the statutory requirement to exclude 340B units. A couple of commenters recommended that CMS engage with interested parties and provide data protections before moving to a

mandatory repository. A few commenters stated that CMS should provide a timeline by which the 340B data collection will transition from voluntary to a mandatory requirement.

A couple of commenters requested CMS work with the HRSA to establish an enforcement mechanism tied to mandatory compliance with the repository. A couple of commenters recommended that CMS consider making data submission to the repository mandatory by relying on its authority at section 1121 of the Act to establish "a uniform system for the reporting," of "discharge and bill data" by facilities and organizations, in addition to general CMS authorities related to organizations enrolled in Medicare. A few commenters recommended CMS make data submission to the repository mandatory by relying on IRA rulemaking authority and general rulemaking authority under sections 1102(a) and 1871(a)(1) of the Act to establish requirements for Medicare providers through Conditions of Participation. These commenters emphasized that covered entities that do not submit data to the repository could be considered to be in violation of the Conditions of Participation and could be subject to a range of actions up to and including termination of their provider agreements.

Response: We are finalizing the proposal to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow us to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program in a future applicable period. We decline to provide a timeline under which we would move to a mandatory repository, but as we stated in the proposed rule, we are actively considering options for mandatory reporting to the 340B repository in the near future and we recommend that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting. We expect that hospitals receiving Medicare DSH payments, FQHCs, and CAHs will begin to submit data elements to the 340B repository during the testing period. We encourage all covered entities to submit data elements to the 340B repository during the testing period beginning in 2026, as this participation would allow for robust testing of data quality and completeness.

We do not agree with the commenters that stated that without a mandatory requirement, the repository will not fulfill the legal requirement to remove 340B units. The repository will not be used at this time to fulfill the legal requirement to remove 340B units, but rather to allow for robust testing of data quality and completeness to allow us to assess whether such data could be used to identify and

remove 340B units for purposes of calculating Part D inflation rebates in a future applicable period following proposal and finalization of a policy to do so. It will also provide an opportunity for covered entities to develop and test their data submission processes. We appreciate the recommendation to engage with interested parties and provide data protections before moving to a mandatory repository, and we plan to continue to engage with interested parties and ensure that data is protected as we consider options for mandatory reporting to the 340B repository.

Finally, we also appreciate the comments and input related to authorities that the agency may rely on to implement a mandatory reporting requirement to the repository and conduct enforcement related to reporting to the repository. We will consider them in connection with any future rulemaking we may undertake with respect to adoption of a mandatory reporting requirement.

Comment: Many commenters stated that data collected in the repository should be used only for inflation rebate purposes. A couple of commenters stated that if CMS were to decide to use data submitted to the repository for other programs outside the Medicare Part D Drug Inflation Rebate Program, CMS should provide ample notice, justification, and an opportunity for interested parties to provide feedback. A commenter requested that CMS clarify if the repository will be integrated with the Medicare Transaction Facilitator Data Module. Another commenter asserted that HHS should not impose two separate and overlapping data submission requirements on covered entities under the 340B repository and HRSA's Rebate Model Pilot Program.

By contrast, some commenters stated that the repository should serve as more than just a resource for the Medicare Part D Drug Inflation Rebate Program and could be a centralized source to identify 340B-eligible claims across HHS programs. A few of these commenters asserted that CMS should work with HRSA to establish a repository with expanded scope that would support transparency across the 340B Program. One of these commenters stated that data submitted to the repository should be used to monitor misuse of the 340B Program by comparing data submitted to the 340B repository to data submitted under HRSA's 340B Rebate Model Pilot Program. Some commenters stated that the information submitted to the repository could be used in the administration of other programs, such as the Medicare Drug Price Negotiation Program. A couple of commenters recommended the repository be

populated with claim-level data from the HRSA 340B Rebate Model Pilot Program for participating drugs.

A commenter expressed interest in how the data submitted to the repository may be used, suggesting that the data the repository would collect could offer significant value if used for public health trends and drug price modeling. This commenter stated they would be supportive of the repository if the goal of the repository was to better track revenue and provide more transparency and accountability to resolve disputes in addition to validating 340B product data.

Response: At this time, any data submitted to the repository will only be used to begin usability testing to assess usability for the purpose of removing 340B units under the Medicare Part D Drug Inflation Rebate Program. If we were to decide to use data submitted to the repository for other programs outside the Medicare Part D Drug Inflation Rebate Program, we will provide notice, justification, and an opportunity for interested parties to provide suggestions on the proposal.

Commenters who recommended the information submitted to the repository could be used in the administration of other programs, these comments are out of scope for this final rule because they address other programs and topics beyond the scope of the Medicare Part D Drug Inflation Rebate Program.

Comment: Many commenters supported the claims data elements that CMS proposed for submission to the 340B repository. Many commenters stated that the five data elements that CMS proposed are appropriate for submission to the repository and do not present overly burdensome requirements or put protected health information at risk. A couple of commenters stated that the proposed data elements represent the necessary information to accurately match to PDE records and that the proposed elements could be easily matched to data from Medicare Part D data to identify 340B units to remove. A couple of commenters recommended CMS minimize the number of data elements for covered entities to submit to the repository. A commenter recommended CMS define data elements and submission timelines for submission to the repository.

Some commenters recommended CMS align the data elements to submit to the repository with the data elements from HRSA's 340B Rebate Model Pilot Program to increase efficiency. A commenter stated that CMS should collect 340B data for all segments of the market rather than only Part D claims, stating that these changes would streamline the submission process for covered entities.

A commenter recommended CMS finalize the data elements proposed with the addition of the "Quantity Dispensed" element. This commenter argued that covered entities tend to submit inaccurate, incomplete, or variable data in the Quantity Dispensed field. A commenter stated that the proposed "Fill Number" data element is not an element routinely collected or used by State and territorial ADAPs and should not be a required field for submission to the repository by State and territorial ADAPs. A commenter recommended CMS add the original purchase date of the units dispensed as an additional data element. A commenter stated that CMS should avoid relying on NPI for prescribers or contract pharmacy identifiers to identify 340B claims, stating that this would likely cause confusion and misidentification. A commenter recommended CMS include prescriber identification as a required data element for submissions to the repository. A couple of commenters recommended that CMS work with interested parties to identify data elements that minimize burden on ADAPs as much as possible.

Response: We intend to minimize burden on covered entities while collecting the minimum elements that would be necessary to match a submission to a PDE transaction to exclude units from inflation rebate calculations, were the repository to be used for such purpose in the future. We appreciate the commenters who submitted recommended additional data elements to collect and the commenters who supported the proposed data elements.

In the interest of minimizing burden on covered entities while collecting sufficient information to match a submission to a PDE transaction to exclude units from inflation rebate calculations, we are finalizing the requirement that entities (whether a 340B covered entity, or a vendor on their behalf) that choose to submit data to the 340B repository during the testing period provide information identifying the 340B covered entity, which could include information such as the covered entity's 340B ID and name as designated in the 340B OPAIS database, when submitting claim information to the 340B repository. In addition to this identifying information, we are finalizing the requirement that covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 must submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service; (2) Prescription or Service Reference Number; (3) Fill Number; (4) Dispensing Pharmacy NPI; and (5) NDC-11. We will use these data elements to match claims to PDE transactions and perform further analyses to assess suitability of the

data for future use in removing 340B units from Part D inflation rebate calculations. In response to the comments regarding ADAP programs and the Fill Number data element, we believe the data elements we are finalizing to collect in the 340B repository minimize burden on covered entities while providing the information needed to match submitted data elements to PDE transactions. For Part D claims, the Fill Number data element is required information to accurately associate the submitted data elements to the correct corresponding PDE record.

Comment: A few commenters stated that submitting data to the repository would not be overly burdensome since entities are already developing infrastructure and operational workflows needed to prepare to submit similar data for a set of drugs that will be included in the HRSA 340B Rebate Model Pilot Program. A commenter supported the proposal to allow third party administrators to transmit that data to the repository on behalf of covered entities.

Some commenters advised CMS to minimize burden on covered entities reporting to the repository. A few commenters stated that the process of identifying claims should not shift costs or burden onto pharmacies or prescribers. A commenter requested CMS finalize the proposal to receive data directly from the covered entity, and not through any payer or manufacturer. A commenter requested that CMS clarify that pharmacies are not required to provide information to the repository, and that only covered entities are voluntarily providing this information.

A commenter interpreted CMS' proposal as requiring covered entities to begin submitting data fields to the 340B repository in 2026, and stated that this requirement would have significant implications for the Indian Health System (IHS) as IHS facilities operate with limited staff and resources and the commenter stated that this data collection could be used to restrict 340B savings. A commenter raised concerns regarding administrative costs and cash-flow volatility for small participants if there are new rebate obligations. A commenter recommended that CMS withdraw the requirement to submit to the repository as it would create an overwhelming administrative burden for rural facilities and stated that CMS should work with payers and pharmacies that already have this data. A commenter raised concern about burden for hospital neurology departments and outpatient practices, stating that the availability of the data elements is variable. This commenter recommended that CMS track additional administrative

burden associated with submitting data to the repository and devise a strategy to minimize burden without reducing the value of the repository.

A few commenters recommended that, to reduce burden on covered entities, CMS remove the proposed requirement that covered entities certify that the data elements submitted are for 340B claims with dates of service during the relevant time period and that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for the applicable period. By contrast, a commenter recommended CMS finalize the proposed provision to require covered entities to complete this certification.

A commenter stated that they do not support the repository because it puts the stability of the 340B Program at risk. A few commenters stated that submitting data to the repository will substantially increase burden on providers and that providers would need to devote significant resources to ensure compliance, which could divert resources from direct patient care. For these reasons, a commenter suggested CMS use the claims-based methodology to identify 340B Part D claims and abandon the repository approach, including any future mandatory data repository. A commenter recommended that CMS allow State ADAP programs to submit direct purchase and rebate data to the repository.

Response: We are finalizing that the 340B repository will be established and will begin accepting voluntary submissions from covered entities of the fields specified by us beginning in 2026 for Part D 340B claims with dates of service on or after January 1, 2026 to allow for us to begin usability testing for the 340B repository. We will not use the data submitted during the testing period to remove units from Part D inflation rebates unless and until a policy to do so is proposed and finalized.

In developing the data elements for submission and process for voluntary submission to the repository, we considered how to minimize burden on covered entities. We do not intend to receive data from pharmacies, manufacturers, or plans on the covered entity's behalf. As we stated in the proposed rule, we understand covered entities typically contract with vendors, such as 340B third-party administrators, to determine 340B-eligibility of claims using data submitted by covered entities and their contractors. We will allow covered entities that choose to submit data to the repository to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf if they

would like to do so. At this time, we are not collecting direct purchase or rebate data in the 340B repository but we note that if ADAPs are covered entities and used 340B drugs for a Part D claim, they can submit the data elements from that claim to the 340B repository.

We appreciate the commenters who submitted comments on the proposed requirement that covered entities certify that the data elements submitted are for 340B claims with dates of service during the relevant time period and that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for the applicable period. We do not have access to data to validate and ensure accuracy of submitted data, therefore we find this certification necessary to ensure completeness and accuracy of data submissions to the 340B repository. We are finalizing the requirement that covered entities must certify the completeness and accuracy of the data submitted.

We do not agree that the 340B repository puts the stability of the 340B Program at risk. A wide array of interested parties commented on the CY 2025 PFS proposed rule and previous CMS policymaking documents recommending that we create a mechanism through which covered entities would retrospectively submit data to us identifying 340B claims dispensed under Part D. Interested parties advised that this mechanism allow covered entities to submit these data directly to us, rather than through claims that dispensers submit via Part D plan sponsors and we believe this structure will not create risk for the 340B Program.

Comment: A few commenters advised CMS to engage with interested parties related to establishing the repository. A commenter encouraged CMS to collaborate with interested parties to ensure that the repository is established effectively and securely so that covered entities can meaningfully participate. A commenter recommended CMS provide a deadline of when the repository will be live and report on its testing of the repository's data matching regularly. A commenter stated that CMS should engage with interested parties to understand why and improve voluntary participation if voluntary reporting to the repository is lower than CMS expected.

A commenter requested that CMS consult with HRSA and provide educational resources and training related to submitting data to the repository that would lower administrative burdens on

pharmacists. A commenter requested that CMS convene an advisory group to assist in finalizing and implementing policy related to ADAPs submitting data to the repository and suggested interested parties to serve as representatives for the group.

Response: We welcome engagement with interested parties, including on topics such as data submission requirements and timing, as we work to operationalize the repository. We will share more information about the repository operationalization as soon as possible and will work to engage with interested parties to understand any barriers to participation, including those representing ADAPs. We will also consider how to provide useful training and resources related to submitting data to the repository that would lower the administrative burdens.

After consideration of public comments, we are adopting the policies as proposed for covered entities to submit 340B claims data to a 340B repository.

4. ICRs Regarding Manufacturers Reporting of Drug Pricing (§§ 414.802, 414.804, and 414.902)

The following proposed changes will be submitted to OMB for review under control number 0938–0921 (CMS–10110)

a. Requiring Certain Manufacturers to Report Drug Pricing Information for Part B (§§ 414.802 and 414.902)

In the CY 2022 PFS final rule, it was stated that the new provisions finalized in that rule at §§ 414.802 and 414.804 implemented new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this proposed rule, hereinafter is referred to as "section 401"), which requires manufacturers without a Medicaid National Drug Rebate Agreement (NDRA) to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological (86 FR 65560). In that final rule, we estimated that an additional 568 respondents had products for which they would be required to report ASP data to CMS beginning January 1, 2022 (86 FR 65560), some of which are manufacturers of skin substitutes. Following the implementation of section 401, we estimated 500 respondents, 2,000 responses (500 respondents x 4 responses/yr), 26,000 hours (2,000 responses x 13 hr/response).

In section II.K. of this final rule, we finalized that skin substitutes be paid as incident-to supplies, which are not required to be paid under section 1847A of the Act. Accordingly, manufacturers of skin substitutes will no longer be required to report ASP data to CMS. Instead, ASP data reporting for manufacturers of skin substitutes would become voluntary. The finalized policy of shifting the payment of skin substitute manufactures to incident-to supplies will therefore decrease the number of manufacturers that are required to report ASP data to CMS each quarter, ultimately decreasing the overall burden of ASP data reporting. Based on ASP data from the April 2025 pricing file, 65 skin substitute manufacturers are reporting ASP data. Under the finalized policy to pay for skin substitute products as incident-to supplies, the number of manufacturers required to report ASP data to CMS would decrease manufacturer burden by minus 65 respondents, minus 260 responses (-65 respondents x 4 responses/yr), and minus 3,380 hours (-260 responses x 13 hr/response) and minus $154,804 (-3,380 hr x $45.80/hr).

TABLE D-A4: Summary Of Total Annual Burden Of Information Collection Request

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	(65)	(260)	13	(3,380)	45.80	(154,804)

We note that these estimates have not changed since the proposed rule.

b. Average Sales Price: Price concessions and Bona Fide Service Fees (§§414.802 and 414.804)

In section III.A of this final rule, we finalized revisions to § 414.804(a)(5) to add additional submission requirements for the reporting of ASP data. Specifically, the submission requirement is being expanded to include (1) reasonable assumptions for calculating the manufacturer's ASP, including a summary of the methodology used to determine fair market value for fee arrangements as described at § 414.804 and (2) warranty or certification letter from the recipient of a fee from a manufacturer as evidence that a fee was not passed on as a price concession in accordance with submission requirements at § 414.804.

Currently, in the absence of specific guidance in the Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices. The

reasonable assumptions explain the methodology used by the manufacturer to calculate ASP. This final rule will make the reasonable assumptions document, which is currently submitted voluntarily by some manufacturers along with ASP data, a required component of the quarterly ASP data submission.

The warranty or certification from the recipient of a bona fide service fee is a new document that we are finalizing to be required as evidence of whether or not a fee was passed on as a discount (that is, price concession).

The burden associated with these new requirements is the time and effort required by manufacturers of drugs and biologicals to submit ASP data to CMS quarterly under sections 1847A and 1927 of the Act and prepare and submit the reasonable assumption document and warrantee/certification letter to CMS.

We anticipate an increase in burden because, in addition to the current requirement for submission of ASP data each quarter to CMS, all manufacturers are required to submit reasonable assumptions and warrantee/certification letters to accompany their ASP data submissions. Because reasonable assumptions varied in terms of the exact information that was provided and were generally updated by each manufacturer every 1 to 3 years depending on changes in the product line and various contract terms and conditions with intermediaries or consultants, we are finalizing adding mandatory templates for submitting reasonable assumptions and bona fide service fee warrantee/certifications.

Consistent with the proposed rule, we continue to anticipate that the number of manufacturers required to report ASP data to CMS will decrease by minus 65 manufacturers (500 active estimate – 435 proposed estimate) and estimate (as described in the following paragraphs) that it will take 77 hours per year for each respondent.

Based on our review of voluntarily submitted reasonable assumption data, we are continuing to estimate that it would take 19 hours annually at $45.80/hr for a Secretary/Administrative Assistant (consisting of 10 hr to compile and/or update the information and 5 hours to review the information approximately once annually and 1 hour per quarter (or 4 hr annually) to submit the reasonable assumptions to CMS to CMS via ASP Data Collection System.

We continue to estimate the disclosure and submission of the warrantee/certification letter from the recipient of a bona fide service fee is 6 hours annually at $45.80/hr for a Secretary/Administrative

Assistant (consisting of 2 hr to review the warrantee/certification letter approximately once per year and 1 hour per quarter (or 4 hr annually)) to submit the warrantee/certification letter, including obtaining a signature, to CMS via the ASP Data Collection System. Although a warrantee/certification letter could be renewed up to every three years depending on the specific terms of each contract, we will use a calculation of once annually to accommodate the burden in most circumstances.

This burden is in addition to the current estimated burden of ASP data submission of 52 hours per year per respondent at $45.80/hr for a Secretary/Administrative Assistant (13 hr per quarter).

In the proposed rule, we estimated that these would result in an annual burden of 25 hours (19 hr + 6 hr) per response per year. In aggregate, we estimate a burden of 10,875 hours (435 responses x 25 hr/response) at an annual cost of $498,075 (10,875 hr x $45.80/hr). This estimate remains the same for this final rule.

We did not receive public comments on these estimates; however, following publication of the proposed rule, we identified that we should account for some additional burden for a chief executive for the certification requirement. Specifically, in this final rule, we are adding burden for certifying ASP data for a chief executive, which would take 1 hour per quarter at $252.82/hr. These additional updates are reflected in Table D-A5.

TABLE D-A5: Annual Requirements And Burden For Manufacturers Reporting Drug Pricing Information For PART B

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804 (new burden associated with reasonable assumptions)	0938-1921 (CMS-10110)	435	4	4.75	19	45.80	378,537
§§ 414.802 and 414.804 (new burden associated with warranty/certification)	0938-1921 (CMS-10110)	435	4	1.5	6	45.80	119,538.
§§ 414.802 and 414.804 (existing burden shifted from administrative assistant so chief executive)	0938-1921 (CMS-10110)	435	4	1	4	252.82	439,907
§§ 414.802 and 414.804 (existing burden reduced by one hour per quarter shifted to chief executive)	0938-1921 (CMS-10110)	435	4	12	48	45.80	956,304
TOTAL (new burden plus active burden)	n/a	435	4	varies	77	varies	1,894,286

5. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out Shared Savings Program burden estimates under this section of the rule. Please refer to the Regulatory Impact Analysis (section VI. of this final rule) for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.F. of this final rule.

6. The Quality Payment Program (42 CFR Part 414 and section IV. of this final rule)

The following Quality Payment Program-specific ICRs reflect changes to our currently approved requirements/burden as summarized in section V.B.5.a.(1) in this final rule.

In the CY 2026 PFS proposed rule (90 FR 32778 through 32793), we presented detailed burden estimates for Quality Payment Program ICRs that are new or revised to reflect the estimated impact of policy proposals. We also discussed policy proposals for Quality Payment Program ICRs for which we assumed there were no burden impacts. In this final rule, we continue this approach for finalized policies. Non-rulemaking revisions, due to updated data and assumptions, and the changes due to provisions of this rule, will be submitted to OMB for approval under the identified control numbers. This approach for the Quality Payment Program ICRs follows our long-standing process for setting out PRA-related burden in most of our proposed and final rules. It is intended to focus our PRA score on the impact of this rule's policy changes. We refer readers to section VII.I.5. of this final rule for the Regulatory Impact Analysis for discussion of this year's policies' impacts to final scores and payment adjustments. For all ICRs, including ICRs where we did not propose changes to the number of respondents, responses, or time per response, the costs identified in the revised collection of information requests reflect the updated 2024 wage rate data described in section V.A. of this final rule.

For the CY 2026 rulemaking cycle, we simplified our methodology for calculating the total cost of each ICR to be consistent with the approach adopted by other programs. In prior years, we assessed total cost as the number of responses multiplied by cost per response, determining cost per response as the time per wage rate category per response multiplied by the hours per response. We removed the cost per response measurement from our total cost calculations and, instead, determined cost as a function of hourly wage rates per labor category identified in Tables D-A1 and D-A2 of this final rule multiplied by the annual hours per labor category. We determined annual hours per labor category by multiplying the

annual burden hours per response by the number of annual responses. Accordingly, we updated our summary calculations of the total change in time and cost of this rulemaking to focus on the estimated incremental burden of this rulemaking.[472]

a. Background

(1) ICRs Regarding the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In section V.B.5.a.(2) of this final rule, we discuss changes in the estimated burden for the information collections associated with the Quality Payment Program. The changes to the estimated burden and the information collections for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey, described in section V.B.5.b.(1) of this final rule, will be submitted to OMB for approval under control number 0938-1222 (CMS-10450). All other changes to burden and information collections for Quality Payment Program ICRs due to policy changes described in this section of the final rule, or the availability of updated data, will be submitted to OMB for approval under control number 0938-1314 (CMS-10621). We did not propose changes to the virtual group election process or burden estimates, currently approved under OMB control number 0938-1343 (CMS-10652).

(a) Summary of Annual Quality Payment Program Burden Estimates

We are finalizing our proposed changes to six Quality Payment Program ICRs due to policies finalized in this final rule. For these six ICRs (five under OMB control number 0938-1314 (CMS-10621) and one under OMB control number 0938-1222 (CMS-10450)), we also updated our burden assumptions based on the updated MIPS participation data. These updated data sources are described in section V.B 5.a.(4)(b) of this final rule. The following paragraphs in this section summarize these changes to our currently approved burden estimates. Detailed discussions per ICR begin in section XX of this final rule.

For ICRs under OMB control number 0938-1314 (CMS-10621), we estimate that the policies finalized in this final rule will result in 2,312 additional responses due to the availability of new MIPS Value Pathways (MVPs). This change reflects the number of historic traditional MIPS submissions we estimate will move to MVP reporting due to the availability of new MVPs and will need to complete a

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[472] Due to this approach to estimate the change in cost, annual changes to the hourly wages rates as identified by BLS are not identified as a change in cost due to data adjustments. Any changes in cost due to data adjustments in section V.B.5.a.(1)(a) of this final rule reflect changes due to the annual hours based on the availability of updated MIPS submission data since our currently approved estimates.

registration form that is not required with traditional MIPS submissions. Accordingly, we estimate the increase in MVP submissions and registrations, and resulting decrease in traditional MIPS submissions will result in an annual decrease of 6,798 hours and $840,757 (see total Policy Change in Tables D-A6, D-A7 and D-A8, respectively) beginning with the CY 2026 performance period/2028 MIPS payment year. In addition, we separately estimate changes to annual burden due to the availability of updated MIPS submission data for these five ICRs since our currently approved estimates will result in an additional annual burden decrease of 5,353 responses, 59,372 hours, and $7,119,526 (see total of Change Due to Updated Data in Tables D-A6, D-A7 and D-A8, respectively). Taken together, we estimate a total reduction of 3,041 responses, 66,169 hours, and $7,960,283 (see total of Total Change in Tables D-A6, D-A7 and D-A8, respectively). All time estimates in the referenced tables are rounded to the hour, and all cost estimates are rounded to the dollar. The change in total time and total cost in the referenced tables per ICR are described in section V.B.5.c. of this final rule and reflect the sum of changes due to policy provisions and newly available data before this rounding. Accordingly, the total change in time per ICR may not equal the sum of changes due to policy and data adjustments because of this rounding. The Total row estimate per table represents the sum of the component ICR rows in that table.

For the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey ICRs under OMB control number 0938-1222 (CMS-10450) (see section V.B.5.b.(1) of this final rule), we estimate that the policy provisions in this final rule will result in an annual change of 0 responses, +10 hours, and +$1,077 (see total of Total Change in Tables D-A9, D-A10, and D-A11, respectively), beginning with the CY 2027 performance period/2029 MIPS payment year.

TABLE D-A6: ANNUAL RESPONSES BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1314 (CMS-10621)

Requirement	Currently Approved Responses*	CMS-1832-F Annual Responses**	Total Change***	Change Due to Policy	Change Due to Updated Data****
Quality Performance Category: Medicare Part B Claims Measure Collection Type (Traditional MIPS)	12,197	8,350	(3,847)	(388)	(3,459)
Quality Performance Category: MIPS CQM and QCDR Measure Collection Type (Traditional MIPS)	17,008	17,407	399	(810)	1,209
Quality Performance Category: eCQM Collection Type (Traditional MIPS)	27,179	23,936	(3,243)	(1,114)	(2,129)
MVP Registration	6,285	8,110	1,825	2,312	(487)
MVP Quality Submission	6,285	8,110	1,825	2,312	(487)

Requirement	Currently Approved Responses*	CMS-1832-F Annual Responses**	Total Change***	Change Due to Policy	Change Due to Updated Data****
Total	68,954	65,913	(3,041)	2,312	(5,353)

*Currently approved annual estimates for CY 2025 performance period/2027 MIPS payment year under OMB Control Number 0938-1314 (CMS-10621).
** Total annual estimate beginning with the CY 2026 performance period/2028 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy changes and updated data.
*** Total impact of policies finalized in this final rule and the availability of updated MIPS submission data.
**** Change reflects the availability of updated MIPS submission data. The currently approved estimate incorporated MIPS submission estimates from the CY 2022 performance period/2024 MIPS payment year. In this final rule, we apply updated MIPS submission data from the CY 2023 performance period/2025 MIPS payment year. For additional information, see section V.B.5.a.(4) of this final rule.

TABLE D-A7: ANNUAL TIME BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1314 (CMS-10621)

Requirement	Currently Approved Total Time (Hours)*	Total Time (Hours)**	Total Change (Hours)***	Change Due to Policy	Change Due to Updated Data****
Quality Performance Category: Medicare Part B Claims Measure Collection Type (Traditional MIPS)	173,197	118,570	(54,627)	(5,510)	(49,118)
Quality Performance Category: MIPS CQM/QCDR Measure Collection Type (Traditional MIPS)	154,484	158,108	3,624	(7,357)	10,981
Quality Performance Category: eCQM Collection Type (Traditional MIPS)	217,432	191,488	(25,944)	(8,912)	(17,032)
MVP Registration	1,571	2,027	456	578	(122)
MVP Quality Submission	40,193	50,515	10,322	14,403	(4,081)
Total	586,877	520,708	(66,169)	(6,798)	(59,372)

* Currently approved annual estimates for CY 2025 performance period/2027 MIPS payment year under OMB Control Number 0938-1314 (CMS-10621).
** Total annual estimate beginning with the CY 2026 performance period/2028 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy changes and updated data.
*** Total impact of policies finalized in this final rule and the availability of updated MIPS submission data. The estimate per ICR applies the change in policy and change in updated data as calculated in section V.B.5.c. of this final rule, before rounding to the full hour as displayed in this table. Thereby, the sum of the "Change Due to Policy" and "Change Due to Updated Data" columns may be one hour different than this estimate due to rounding. The "Total" row is the sum of the preceding rows in this table.
**** This change reflects the change in hours due to the updated number of estimated responses due to the availability of updated MIPS submission data (independent of the finalized policy to add six new MVPs). The currently approved estimate incorporated MIPS submission estimates from the CY 2022 performance period/2024 MIPS payment year. In this final rule, we apply updated MIPS submission data from the CY 2023 performance period/2025 MIPS payment year.

TABLE D-A8: ANNUAL COST BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1314 (CMS-10621)

Requirement	Total Change in Cost*	Change Due to Policy	Change Due to Updated Data**
Quality Performance Category: Medicare Part B Claims Measure Collection Type (Traditional MIPS)	($6,496,552)	($655,228)	($5,841,324)
Quality Performance Category: MIPS CQM/QCDR Collection Type (Traditional MIPS)	$444,109	($901,575)	$1,345,684
Quality Performance Category: eCQM Collection Type (Traditional MIPS)	($3,231,520)	($1,110,056)	($2,121,463)
MVP Registration	$49,120	$62,227	($13,108)
MVP Quality Submission	$1,274,560	$1,763,875	($489,315)
Total	($7,960,283)	($840,757)	($7,119,526)

* This change reflects the change in cost due to the total change in hours (determined as the sum of change in hours multiplied by hourly wages, per labor category). This change incorporates changes due to policy and due to updated data. The estimate per ICR applies the change in policy and change in updated data as calculated in section V.B.5.c. of this final rule, before rounding to the full dollar as displayed in this table. Thereby, the sum of the "Change Due to Policy" and "Change Due to Updated Data" columns may be one dollar different than this estimates due to rounding. The "Total" row is the sum of the preceding rows in this table.
**This change reflects the change in dollars due to the updated number of estimated responses due to the availability of updated MIPS submission data (independent of the finalized policy to add six new MVPs). The currently approved estimate incorporated MIPS submission estimates from the CY 2022 performance period/2024 MIPS payment year. In this final rule, we apply updated MIPS submission data from the CY 2023 performance period/2025 MIPS payment year.

TABLE D-A9: ANNUAL RESPONSES BEGINNING WITH THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1222 (CMS-10450)

Requirement	Currently Approved Responses*	Responses**	Total Change in Responses	Change Due to Policy	Change Due to Updated Data
CAHPS for MIPS Survey Vendor Application	10	10	0	0	0

* Currently approved annual estimates under OMB Control Number OMB control number 0938-1222 (CMS-10450).
** Total annual responses beginning with the CY 2027 performance period/2028 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy adjustments and updated data.

TABLE D-A10: ANNUAL TIME BEGINNING WITH THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1222 (CMS-10450)

Requirement	Currently Approved Total Time (Hours)*	Time Per Response**	Total Time (Hours)***	Total Change in Time (Hours)****	Change in Total Time (Hours) Due to Policy	Change in Total Time (Hours) Due to Updated Data*****
CAHPS for MIPS Survey Vendor Application	100	11	110	10	10	0

* Currently approved annual estimates under OMB Control Number OMB control number 0938-1222 (CMS-10450).
** Total annual time per response beginning with the CY 2027 performance period/2028 MIPS payment year.
*** Total annual estimate beginning with the CY 2027 performance period/2029 MIPS payment year, reflecting the currently approved estimate and the total change due to both policy changes and updated data.
**** Total impact of policies finalized in this final rule and the availability of updated MIPS submission data.
***** We did not change our currently approved estimates due to the availability of updated data that is independent of the impacts of finalized policies.

TABLE D-A11: ANNUAL COST BEGINNING WITH THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR UNDER OMB CONTROL NUMBER 0938-1222 (CMS-10450)

Requirement	Total Change in Cost*	Change in Cost Due to Policy	Change in Cost Due to Updated Data
CAHPS for MIPS Survey Vendor Application	$1,077	$1,077	N/A

* This change reflects the change in cost due to the total change in hours (determined as the sum of change in hours multiplied by hourly wages, per labor category). This change incorporates changes due to policy and due to updated data.

(2) Summary of Changes for the Quality Payment Program: MIPS

(a) MIPS ICRs with Changes Due to Policy Provisions

For the six ICRs detailed in Tables D-A6 through D-A13, we are finalizing our proposed burden changes based on policies finalized in this final rule as well as updated data available when preparing the CY 2026 PFS proposed rule. These discussions begin in section V.B.5.b. of this final rule.

(b) MIPS ICRs with No Changes to Currently Approved Burden Estimates

In the CY 2026 PFS proposed rule (90 FR 32782), we did not propose to update our burden estimates for the following ICRs under OMB control number 0938-1314 (CMS-10621) because there were no proposed policies that affect our currently approved burden estimates, and we did not have updated available data by which to revise our currently approved burden estimates for respondents or hours: (1) Nomination of Improvement Activities; (2) Nomination of MVPs; (3) Opt-out of Performance Data Display on Compare Tools for Voluntary Participants; (4) Subgroup Registration; (5) Qualified Clinical Data Registry (QCDR) Full Self Nomination and other Requirements; (6) QCDR Simplified Self-Nomination and other Requirements; (7) Qualified Registry Full Self Nomination and other Requirements; (8) Qualified Registry Simplified Self Nomination and other Requirements; and (9) Third Party Intermediary Plan Audits. Additionally, we did not propose changes to our burden response and hour estimates for the following ICRs under OMB control number 0938-1222 (CMS-10450): (1) Beneficiary Responses to CAHPS for MIPS Survey; and (2) Group Registration for CAHPS for MIPS Survey. Lastly, we did not propose changes to our burden estimates for Registration for Virtual Groups under OMB control number 0938-1343 (CMS-10652). Where applicable, we discuss related policy provisions finalized in this final rule and the reasoning for not impacting our burden estimates per ICR, beginning in section V.B.5.b.(2) of this final rule.

(c) MIPS ICRs with Changes Due to Available Data

Separate from the policies finalized in section IV. of this final rule and ICRs described in Tables D-A6 through D-A11, we identified in the CY 2026 PFS proposed rule (90 FR 32782) that we are updating our burden estimates for the following ICRs for the CY 2026 performance period/2028 MIPS payment year due to the availability of updated data. Since the changes were not derived from policy provisions, we do not set out these changes in this final rule : (1) Call for Quality Measures; (2) Data Submission for the Improvement Activities Performance Category; (3) Data Submission for the Promoting Interoperability Performance Category; (4) Open Authorization (OAuth) Credentialing and Token Request Process; (5) Quality Payment Program Identity Management Application Process; and (6) Reweighting Applications for Promoting Interoperability and Other Performance Categories.

Where applicable, we discuss any related policies finalized in this final rule and our reasoning for why these policies do not impact our burden estimates per ICR, beginning in section V.B 5.d.(2) of this final rule.

(d) New MIPS ICRs

The following changes will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

In the CY 2026 PFS proposed rule (90 FR 32782 and 32783), we proposed to add a new ICR to reflect submissions for the Alternative Payment Model Performance Pathway (APP), due to the availability of updated data. The APP is an optional MIPS reporting and scoring pathway for MIPS eligible clinicians who are also participants in MIPS APMs, as defined at § 414.1367. Our burden estimates for the APP focus on submissions by individuals, groups, or non-Shared Savings Program ACO APMs for the APP quality measure set. As there were no related policy provisions affecting these estimates, we did not detail the APP burden estimates in the CY 2026 PFS proposed rule.

We did not estimate burden for Shared Savings Program ACOs under the APP. Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Additionally, we did not establish an ICR for the APP Plus quality measure set. In the CY 2025 PFS final rule (89 FR 98355 through 98371), we established the APP Plus as a new quality measure set designed for APP participants that expands the existing APP measure set and is mandatory for Shared Savings Program ACOs starting in the CY 2025 performance period/2027 MIPS payment year. We continued our assumption from the CY 2025 PFS final rule (89 FR 98549 and 98550) that MIPS eligible clinicians, groups, and APM Entities (excluding Shared Savings Program ACOs) will not elect to submit the APP Plus quality measure set. This assumption is because the APP Plus quality measure set has greater reporting requirements than the APP quality measure set. The APP Plus quality measure set for CY 2026 performance period/2028 MIPS payment year finalized in the CY 2025 PFS final rule (89 FR 98368) requires that MIPS eligible clinicians, groups, or non-Shared Savings Program ACOs actively report five quality measures (via the eCQM, MIPS CQM, and Part B Claims collection types as available per measure for non-Shared Savings Program ACOs per measure) instead of three quality measures in the APP quality measure set that are actively reported via the MIPS

CQM, part B Claims and eCQM collection types, as available per measure for non-Shared Savings Program ACOs. We do not believe MIPS eligible clinicians, groups, and APM Entities who are not required to report the APP Plus quality measure set will elect to report APP Plus over APP quality measure set due to the increased data collection and submission requirements.

(3) Summary of Changes for the Quality Payment Program: Advanced APMs

In the CY 2026 PFS proposed rule (90 FR 32783), we did not propose changes to the following ICRs due to policy provisions or the availability of updated submission data beyond the wage rate data described in section V.A. of this final rule: (1) Partial Qualifying Advanced APM (QP) Elections; (2) Other Payer Advanced APM Determinations: Payer-Initiated Process; (3) Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process; and (4) Submission of Data for QP Determinations under the All-Payer Combination Option. We discuss related policy provisions and why they do not impact our burden estimates in sections V.B 5.a.(4)(c) and VII.I.5.e.(2)(b) of this final rule.

(4) Framework for Understanding the Burden of MIPS Data Submission and Data Considerations

(a) Framework for Understanding the Burden of MIPS Data Submission

Across organizations permitted or required to submit data on behalf of clinicians, there can be variation across the types of data provided, and whether a clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, a MIPS APM participant, or an Advanced APM participant. MIPS eligible clinicians and other clinicians voluntarily submitting data to MIPS for the quality, Promoting Interoperability, and improvement activities performance categories may submit data as the following participation types: individual; group; virtual groups (available only for traditional MIPS); subgroups (available only for MVPs); and APM Entities. Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS. MIPS eligible clinicians are not required to submit any additional data for the cost performance category, as CMS calculates performance on measures specified for this performance category based on claims-data.

Virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted.

For the aforementioned participation types, we assessed the same burden per reporting option and assumed from our available data that all non-Shared Savings Program ACO APM Entity submissions

represent single Taxpayer Identification Number (TIN) APMs. We excluded performance category submissions by Shared Savings Program ACO APM Entities from our MIPS reporting estimates. Per section 1899(e) of the Act, the PRA does not apply to the Shared Savings Program. The regulatory impact analysis in section VII. of this final rule discusses impacts to the Shared Savings Program from provisions associated with this final rule.

There are three MIPS reporting options: traditional MIPS, MVPs, and the APP. In section V.B.5.c. of this final rule, we provide distinct estimates for the traditional MIPS and MVP reporting options for the quality performance category, focusing on changes to our currently approved burden estimates. We do not detail burden estimates for the Promoting Interoperability and improvement activities performance categories because we are not finalizing any updates to our burden estimates associated with policy provisions of this final rule; for discussion of these provisions relative to burden implications, please see sections V.B.5.d. and V.B.5.e. of this final rule. As with the CY 2026 PFS proposed rule (90 FR 32783), we have not separately estimated burden for traditional MIPS and MVPs for the Promoting Interoperability and improvement activities performance categories. Traditional MIPS and MVPs require reporting on all Promoting Interoperability performance category objectives and measures. Traditional MIPS reporting for the improvement activities performance category typically requires attestation to two improvement activities; however, clinicians, groups, and virtual groups with a special status designation are only required to attest to one improvement activity. MVP participants are required to attest to one improvement activity regardless of special status. For additional details on historic burden assumptions for the improvement activities performance category, we refer readers to the CY 2025 PFS final rule (89 FR 98492). In the related collection of information request (OMB control number 0938-1314 (CMS-10621)), we aggregate submissions across all reporting options. For additional burden historic frameworks, we refer readers to the CY 2024 PFS final rule (88 FR 79422 through 79424) and the CY 2025 PFS proposed rule (89 FR 62111 through 62114).

(b) Summary of Available MIPS Submission Data Sources

Where available, we incorporated updated data into our burden estimates beginning with the CY 2026 performance period/2028 MIPS payment year. These updates include submission data from the CY 2023 performance period/2025 MIPS payment year. To estimate QPs excluded from MIPS reporting

requirements, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot for the 2023 QP Performance period.

The available CY 2023 performance period/2025 MIPS payment year data identifies performance category submissions by non-Shared Savings Program ACO APM Entities. We incorporated these estimates alongside our longstanding inclusion of individual, group, and virtual group data.

As detailed in section V.B.5.c.(6) of this final rule, we updated our assessment of estimated MVP quality performance category submissions and registrations. We assessed measure-level submission trends from the CY 2023 performance period/2025 MIPS payment year (87 FR 70650 through 70701) alongside the MVP inventory finalized in the CY 2025 PFS final rule Appendix 3 (89 FR 98972 through 99057), and the new MVPs finalized as proposed in section IV.A.4.a.(1) of this final rule. The CY 2023 performance period/2025 MIPS payment year submission data include MVP submissions and registration for the 12 MVPs available at that time for MIPS reporting. Due to the expanded MVP inventory (16 MVPs available for the CY 2024 performance period/2026 MIPS payment year (88 FR 79978 through 80047), 21 MVPs available for the CY 2025 performance period/2027 MIPS payment year (89 FR 98972 through 99057)), and 27 MVPs as finalized in this final rule for the CY 2026 performance period/2028 MIPs payment year, we anticipate increased MVP adoption for the CY 2026 performance period/2028 MIPS payment year and beyond. We estimated MVP submissions as a percentage of the total traditional MIPS and MVP submissions from the CY 2023 performance period/2025 MIPS payment year. For details on this analysis, we refer readers to section V.B.5.c.(6) of this final rule.

(c) Additional Data Considerations

The accuracy of our estimates of the total burden for data submission for MIPS performance categories may be impacted by several primary factors. First, we are unable to predict with certainty who will be a QP for the CY 2026 performance period/2028 MIPS payment year and later years.

Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2026 performance period/2028 MIPS payment year or later years compared to the CY 2023 performance period/2025 MIPS payment year. Therefore, the actual number of Advanced APM participants and how they elect to submit data may differ from our estimates. However, we believe our estimates are the most appropriate given the available data. We refer readers to section VII.I.5.e.(2)(b) of

this final rule for a discussion of the potential but unquantifiable burden implications on MIPS-related burden of the provisions to change QP determinations and remove the eligible clinician limit to the Medical Home Model, Aligned Other Payer Medical Home Model, and Medicaid Medical Home Model, finalized in section IV.B.5. of this final rule.

In section IV.B.5.d. of this final rule, we are finalizing our proposal to make a technical amendment to the language in § 414.1455 that establishes Targeted Review for QPs. This provision revises the timeline but not the other established processes for requested a targeted review. We note that information collection requirements, such as targeted reviews, that are imposed after an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2).

b. ICRs Regarding Third Party Intermediaries

(1) CMS-Approved Survey Vendor Requirements

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey. We refer readers to the CY 2024 PFS final rule (88 FR 79433 through 79434) and the CY 2025 PFS final rule (89 FR 98475) for recent burden discussions on this ICR. The following changes (associated with CAHPS survey vendors to submit data for eligible clinicians) will be submitted to OMB for approval under control number 0938-1222 (CMS-10450). We will make the revised files available for public review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices, which are expected to publish in the CY 2026 performance period/2028 MIPS payment year.

As discussed in section IV.B.4.a.(5) of this final rule, we are finalizing our proposal to add a web administration mode to the current CAHPS for MIPS Survey administration in addition to the existing mail and phone options. Beginning with the CY 2027 performance period/2029 MIPS payment year, CMS-approved survey vendors are required to administer the CAHPS for MIPS Survey via a web-mail-phone protocol. During the 1-year implementation delay, we will update the survey administration requirements and associated materials.

For the CY 2027 performance period/2029 MIPS payment year, we proposed to increase the currently approved burden estimate of 10 hours to complete the vendor application by 1 hour for a total of 11 hours per application (90 FR 32784). The currently approved burden estimate for the vendor

application includes completing the Vendor Attestation Statement, the Vendor Participation Form, and compiling documentation, including the quality assurance plan that demonstrates compliance with the Minimum Survey Vendor Business Requirements. We estimate that it will take applicants an additional 0.5 hours to compile documentation related to the web mode and an additional 0.5 hours to develop a quality assurance plan related to web implementation. We assumed that our proposal to add a web administration mode to the current CAHPS for MIPS survey administration will not affect our currently approved estimate of 10 survey vendor applicants. We estimate an annual increase of 10 hours due to this proposed requirement (+1 hr/vendor × 10 vendors) at a cost of +$1,077 (10 hr × $107.66/hr for a computer systems analyst or equivalent). We have summarized the comments we received about the proposal to add the web administration mode in section XX of this final rule. We did not receive public comments about these burden estimates.

TABLE D-A12: ANNUAL REQUIREMENT AND BURDEN ESTIMATES FOR CMS-APPROVED SURVEY VENDORS

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1400 Quality Payment Program: CAHPS for MIPS Survey	0938-1222 (CMS-10450)	10	10	1	10	107.66	1,077

(2) Full and Simplified Self-Nomination for Qualified Clinical Data Registries and Qualified Registries

In section IV.A.4.a.(3) of this final rule, we are finalizing our proposal to provide additional flexibilities to allow third party intermediaries additional time to fully support finalized MVPs. The provision does not alter requirements related to the self-nomination process, therefore we did not propose revisions in the CY 2026 PFS proposed rule (90 FR 32784) to our currently approved responses and time per response for both the Full and Simplified Self-Nominations for Qualified Registries and Qualified Clinical Data Registries under OMB control number 0938-1314 (CMS-10621).

c. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Changes to Quality Performance Category Submissions

As discussed in the CY 2026 PFS proposed rule (90 FR 32784 through 32786), we estimated the number of submissions for each collection type that require active reporting by individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program ACO APM Entities. This includes Medicare Part B claims measures (individual clinicians only), MIPS Clinical

Quality Measures (CQM) and QCDR measures, and electronic Clinical Quality Measures (eCQM). Notably, we did not assess burden for the quality administrative claims collection type, as CMS automatically calculates scores for individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program ACO APM Entities that meet requirements to be scored. We assumed that the proposal to revise QP determinations, finalized with modification in section IV.B.5.b. of this final rule, does not affect MIPS performance category-level data submissions. For additional discussion of this assumption, we refer readers to section XX of this final rule.

Because MIPS eligible clinicians may submit data for multiple collection types for the quality performance category, the estimated numbers of individual clinicians, groups, subgroups (as applicable for MVP reporting), and non-Shared Savings Program ACO APM Entities to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians, groups, subgroups (as applicable for MVP reporting) and non-Shared Savings Program ACO APM Entities that collected and submitted data via multiple collection types or reporting options during the CY 2023 performance period/2025 MIPS payment year. We describe our approach for each MIPS reporting option below.

(a) Traditional MIPS

As described in the CY 2026 PFS proposed rule (90 FR 32785), we estimated the number of traditional MIPS submissions for the CY 2026 performance period/2028 MIPS payment year as the sum of estimated traditional MIPS and MVP quality performance submissions from the CY 2023 performance period/2025 MIPS payment year for each actively submitted collection type (Medicare Part B claims measures, MIPS CQMs and QCDR measures, and eCQMs) submitted by individual clinicians, groups, or non-Shared Savings Program APM Entities individual, less the estimated number of submissions we expect to submit MVPs. This analysis is described in section V.B.5.c.(6) of this final rule.

(b) MVPs

As described in the CY 2026 PFS proposed rule (90 FR 32785), we estimated the number of MVP submissions for the CY 2026 performance period/2028 MIPS payment year as a percent of the total traditional MIPS and MVP submissions from the CY 2023 performance period/2025 MIPS payment year for each actively submitted collection type (Medicare Part B claims measures, MIPS CQMs and QCDR

measures, and eCQMs) by individual clinicians, groups, or non-Shared Savings Program ACO APM Entities, and add our estimate of subgroup submissions described in section V.B.5.c.(6) of this final rule. We believe this approach to estimate MVP submissions as a function of historic traditional MIPS and MVP submissions, and not just MVP submissions from a given year, is appropriate to estimate future reporting behaviors because we expect increased adoption due to the annual expansion of and updates to the MVP inventory as summarized in section IV.A.4.a. of this final rule. This analysis is described in section V.B.5.c.(6) of this final rule.

(c) APM Performance Pathway (APP)

We assumed the number of submissions per available collection type that is actively reported by clinicians, groups, or non-Shared Savings Program APM ACO Entities. We do not detail these estimates in this final rule as there are no changes due to policy provisions.

(d) Factors Affecting Quality Performance Category Submission Estimates

Several factors drove our updates to the number of submissions for the Medicare Part B claims measures, MIPS CQMs and QCDR measures, and eCQMs, as presented in the CY 2026 PFS proposed rule (90 FR 32785). First, we incorporated updated traditional MIPS and MVP submission data available for the CY 2023 performance period/2025 MIPS payment year. For the CY 2025 PFS final rule (89 FR 98475), our available submission data for the CY 2022 performance period/2024 MIPS payment year included only traditional MIPS submissions. We aggregated submissions for both traditional MIPS and MVPs by collection type and created a new baseline to which we applied our MVP participation estimates for the CY 2026 performance period/2028 MIPS payment year. Please see section V.B 5.a.(4) of this final rule for additional details on updates to available data.

Second, we proposed to updated our estimates for MVP participation for the CY 2026 performance period/2028 MIPS payment year. This updated estimate for MVP participation impacted our estimate of the number of estimated clinicians submitting quality data for traditional MIPS using each collection type. As detailed in section V.B.5.c.(6) of this final rule, we updated our estimates to account for the expected increase in MVP participation of 4 percentage points due to the finalized addition of six new MVPs in this final rule; we associated this incremental effect, all else equal, with policy provisions. With this approach, any increase to our expected MVP participation rate reduces the number of estimated

submissions for each quality performance category collection type via traditional MIPS. Similarly, any decrease to our estimated MVP participation rate increases the number of estimated submissions for each quality performance category collection type via traditional MIPS.

(e) Medicare Part B Claims Measure, MIPS CQMs/QCDR Measure, and eCQM Collection Types

Table D-A13 of this final rule identifies our methods to estimate the number of individual clinicians, groups, and non-Shared Savings Program ACO APM Entities that may submit data via each collection type in the CY 2026 performance period/2028 MIPS payment year, separating traditional MIPS and MVP estimates. As presented in the CY 2026 PFS proposed rule (90 FR 32785 through 32786), we identify estimated submissions per collection type from CY 2023 performance period/2025 MIPS payment year data (row a). We estimated that 14 percent of these quality performance category submissions may report via MVPs for the CY 2026 performance period/2028 MIPS payment year (row b). This 14 percent encompasses our estimate that 10 percent of submissions will report the MVPs previously finalized in the CY 2025 PFS final rule (row c), and that 4 percent of submissions will submit the new MVPs finalized in this final rule (row d). The basis of these assumptions is described in section V.B.5.c.(6) of this final rule.

In the following paragraphs, we discuss the impacts to the estimated number of submissions for traditional MIPS, aggregated across individual clinician, group, and non-Shared Savings Program APM Entity submissions where applicable per collection type. We discuss the impacts to the estimated number of submissions for MVPs in section V.B.5.c.(6) of this final rule. For each collection type, we assume there is one annual submission or response per respondent.

Medicare Part B Claims Measure Collection Type:

In the CY 2025 PFS final rule (89 FR 98479 through 98481), we estimated 12,197 submissions. For the CY 2026 performance period/2028 MIPS payment year we estimate 3,459 fewer submissions for this collection type via traditional MIPS due to the availability of updated submission data and assumptions. Additionally, we estimate that the six new MVPs finalized as proposed in section XX of this final rule will result in 388 fewer traditional MIPS submissions for this collection type, as the availability of new MVPs may lead clinicians who previously reported via traditional MIPS to report via MVPs. We estimate that there will be approximately 8,350 Medicare Part B claims measure collection

type submissions for the CY 2026 performance period/2028 MIPS payment year submitted by individual clinicians. Taken together, we estimate a total decrease of 3,847 submissions (-388 submissions due to policy provisions + -3,459 submissions due to updated data). The net result is 8,350 submissions (12,197 currently approved submissions - 3,847 submissions).

The aforementioned changes, as presented in the CY 2026 PFS proposed rule (90 FR 32785), apply to OMB control number 0938-1314 (CMS-10621). We did not receive public comment on these submission estimates and are finalizing these burden estimates as proposed. We calculated the impact of these updated submission estimates on total annual cost and total hours per participation option and collection type in section XX of this final rule.

MIPS CQM and QCDR Measure Collection Types:

In the CY 2025 PFS final rule (89 FR 98481 through 98483), we estimated 17,008 submissions. For the CY 2026 performance period/2028 MIPS payment year we estimate 1,209 more submissions for this collection type via traditional MIPS due to the availability of updated submission data and assumptions. Additionally, we estimate that the new MVPs finalized as proposed in section IV.A.4.a.(1) of this final rule will result in 810 fewer traditional MIPS submissions for this collection type, as the availability of new MVPs may lead clinicians who previously reported via traditional MIPS to report via MVPs. We estimate that there will be approximately 17,407 MIPS CQM/QCDR measure collection type submissions for the CY 2026 performance period/2028 MIPS payment year (11,266 individual clinicians + 6,132 groups + 9 non-Shared Savings Program ACO APM Entities). This is a total increase of 399 submissions (1,209 submissions due to updated data + -810 submissions due to policy provisions). The net result is 17,407 submissions (17,008 currently approved submissions + 399 submissions). Given the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQMs or QCDR measures.

The aforementioned changes, as presented in the CY 2026 PFS proposed rule (90 FR 32786), apply to OMB control number 0938-1314 (CMS-10621). We did not receive public comment on these submission estimates and are finalizing these burden estimates as proposed. We calculate the impact of these updated submission estimates on total annual cost and total hours per participation option and collection type in section XX of this final rule.

eCQM Collection Type:

In the CY 2025 PFS final rule (89 FR 98483 to 98485), we estimated 27,179 submissions. For the CY 2026 performance period/2028 MIPS payment year we estimate 2,129 fewer submissions for this collection type via traditional MIPS due to the availability of updated submission data and assumptions. Additionally, we estimate that the new MVPs finalized as proposed in section IV.A.4.a.(1) of this final rule will result in 1,114 fewer traditional MIPS submissions for this collection type, as the availability of new MVPs may lead clinicians who previously reported via traditional MIPS to report via MVP. We estimate that there will be approximately 23,936 eCQM collection type submissions for the CY 2026 performance period/2028 MIPS payment year (approximately 18,282 individual clinicians + 5,647 groups + 7 non-Shared Savings Program ACO APM Entities). This is a total decrease of 3,243 submissions (-2,129 submissions due to updated data + -1,114 submissions due to policy provisions). The net result is 23,936 submissions (27,179 currently approved submissions - 3,243 submissions).

The aforementioned changes, as presented in the CY 2026 PFS proposed rule (90 FR 32786), apply to OMB control number 0938-1314 (CMS-10621). We did not receive public comment on these submission estimates, and are finalizing these burden estimates as proposed. We calculate the impact of these updated submission estimates on total annual cost and total hours per participation option and collection type in section XX of this final rule.

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR measure collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table D-A13 are not mutually exclusive. We assume that each response or submission per collection type for traditional MIPS includes six quality measures, and that each response or submission per collection type for MVPs includes four quality measures.

TABLE D-A13: ESTIMATED NUMBER OF SUBMISSIONS FOR QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

Burden and Submission Description	Medicare Part B Claims Measure	MIPS CQM/QCDR Measure	eCQM
2026 MIPS Performance Period (Excludes QPs) Before Applying Estimated MVP Submission Rate (a)	9,709	20,241	27,833
Total Estimated MVP Submissions (14%) (b) = (a) × - 0.14 or (c) + (d)	(1,359)	(2,834)	(3,897)
Estimate for CY 2025 Approved MVPs (10 percent) (c)= (a) × -0.10	(971)	(2,024)	(2,783)
Estimate for MVPs Finalized in the CY 2026 Final Rule (4 percent) (d) = (b) - (c)	(388)	(810)	(1,114)
2026 MIPS Performance Period (Excludes QPs and Estimated MVP Submissions) (e) = (a) + (b)	8,350	17,407	23,936
2025 MIPS Performance Period from CY 2025 PFS Final Rule (Excludes QPs) (f)	12,197	17,008	27,179
Difference in Number of Submissions (g) = (e) − (f)	(3,847)	399	(3,243)
Change Due to Policies in the CY 2026 Final Rule (h) = (d)	(388)	(810)	(1,114)
Change Due to Availability of Updated Data (i) = (g) – (h)	(3,459)	1,209	(2,129)

(2) Additional Burden Assumptions for the Quality Performance Category

For a discussion of the longstanding burden assumptions and any related limitations associated with the submission of quality performance category data, we refer readers to the CY 2025 PFS final rule (89 FR 98478 and 98479). We refer readers to the CY 2022 PFS final rule for details on MVP quality reporting requirements (86 FR 65411 through 65412).

As described in section IV.A.4.d.(1)(c)(iii) of this final rule, for the quality performance category, we are finalizing our proposal with modification to update the MIPS quality measure inventory; and are revising the definition of a high priority measure. As described in section IV.A.4.b.(2) of this final rule, we are finalizing our proposal to incorporate the updated versions of the MIPS quality measures used in the APP quality measure set. As these provisions do not affect the minimum reporting requirements for the quality performance category under traditional MIPS, MVPs, and the APP quality measure set, we did not propose burden changes for the Quality Payment Program (90 FR 32786) . We refer readers to Table Group A of Appendix 1 for the finalized new measures; Table Group C of Appendix 1 for the finalized removed measures; and Table Groups D and DD of Appendix 1 for the finalized substantive changes to measures.

In sections V.B.5.c.(3), V.B.5.c.(4), and V.B.5.c.(5) of this final rule, we detail the estimated burden changes per collection type for traditional MIPS, and in section V.B.5.c.(6) for MVPs finalized in this rulemaking. As noted in section V.B.5.a.(4) of this final rule, we revised our estimates described in the CY 2025 PFS final rule due to : (1) the availability of updated performance category data; (2) the inclusion of data estimates for non-Shared Savings Program ACO APM Entities; and (3) the new MVPs.

(3) Traditional MIPS Quality Data Submission by Clinicians: Medicare Part B Measure Collection Type

The following changes, as presented in the CY 2026 PFS proposed rule (90 FR 32787), will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 70149 through 70151) and the CY 2025 PFS final rule (89 FR 98479 through 98481). As with the CY 2025 PFS final rule (89 FR 98479 through 98481), we acknowledge a range of times for computer system analysts to submit quality measure data (minimum, mean, and maximum burden estimates) for this collection type. We continue to apply the maximum burden in our total burden estimates. All changes to the number of quality performance category submissions as described in this section are relative to our currently approved estimate of 12,197 submissions detailed in the CY 2025 PFS final rule (89 FR 98479 through 98481).

Impact of Policy Provisions: We estimate a change of -388 submissions due to finalizing six new MVPs in this final rule. Multiplying the estimated change in submissions (-388) by the time per submission by labor category, we estimate a maximum total change of minus 5,509.60 hours. All estimates encompass time to review measure specifications unless otherwise noted. This change of -5,509.60 hours incorporates the following estimates:

- Minimum of -446.20 hours for computer system analysts (-388 submissions × 1.15 hr/submission (0.15 hr to submit data and 1 hr to review measure specifications)).
- Mean of -795.40 hours for computer system analysts (-388 submissions × 2.05 hr/submission (1.05 hr to submit data and 1 hr to review measure specifications)).
- Maximum of -3,181.60 hours for computer system analysts (-388 submissions × 8.2 hr/submission (7.2 hr to submit data and 1 hr to review measure specifications)).
- -1,164 hours for medical and health service managers (-388 submissions × 3 hr/submission).
- -388 hours for licensed practical nurses (LPNs) (-388 submissions × 1 hr/submission).
- -388 hours for billing clerks (-388 submissions × 1 hr/submission).
- -388 hours for physicians (-388 submissions × 1 hr/submission).

We estimate a maximum annual change of minus $655,228.02 [(-3,181.602 hr × $107.66/hr = -$342,531.06 for computer system analysts) + (-1,164 hr × $132.44/hr = -$154,160.16 for medical and health service managers) + (-388 hr × $61.68/hr = -$23,931.84 for LPNs) + (-388 hr × $47.60/hr = -$18,468.80 for billing clerks) + (-388 hr × $299.32/hr = -$116,136.16 for physicians)].

Impact of Updated Data: We estimate an additional change of -3,459 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (-3,459) by the time per submission identified by labor category in preceding list, we estimate a maximum total change of -49,117.808 hours. This change incorporates the following estimates:

- Minimum of -3,997.85 hours for computer system analysts (-3,459 submissions × 1.15 hr/submission).
- Mean of -7,090.95 hours for computer system analysts (-3,459 submissions × 2.05 hr/ submission).
- Maximum of -28,363.80 hours for computer system analysts (-3,459 submissions × 8.2 hr/submission).
- -10,377 hours for medical and health service managers (-3,459 submissions × 3 hr/submissions).
- -3,459 hours for LPNs (-3,459 submissions × 1 hr/submission).
- -3,459 hours for billing clerks (-3,459 submissions × 1 hr/submission).
- -3,459 hours for physicians (-3,459 submissions × 1 hr/submission).

We estimate a maximum annual change of -$5,841,323.994 [(-28,363.80 hr × $107.66/hr = -$3,053,646.71 for computer system analysts) + (-10,377 hr × $132.44/hr = -$1,374,329.88 for medical and health service managers) + (-3,459 hr × $61.68/hr = -$213,351.12 for LPNs) + (-3,459 hr × $47.60/hr = -$164,648.40 for billing clerks) + (-3,459 hr × $299.32/hr = -$1,035,347.88 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and newly available data will result in a change of minus 3,847 submissions (-388 due to policy provisions + -3,459 due to updated data), a maximum annual burden change of minus 54,627 hours (-5,509.60 hr due to policy provisions + -49,117.80 hr due to updated data, rounded to the hour) and minus $6,496,552 (-$655,228.02 due to policy provisions + -$5,841,323.994 due to updated data). We

estimate a total of 8,350 traditional MIPS submissions under the Medicare Part B collection type for the CY 2026 performance period/2028 MIPS payment year.

We did not receive public comments on our burden estimates and assumptions, and therefore, we are finalizing our burden estimates as proposed.

(4) Traditional MIPS Quality Data Submission: MIPS CQM and QCDR Measure Collection Types

The following changes, as presented in the CY 2026 PFS proposed rule (90 FR 32787 through 32788), will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

These estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians, groups, and non-Shared Savings Program ACO APM Entities. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 70149 through 70151) and the CY 2025 PFS final rule (89 FR 98479 through 98483). All estimates encompass time to review measure specifications unless otherwise noted. All changes to the number of quality performance category submissions described below are relative to our currently approved estimate of 17,008 submissions detailed in the CY 2025 PFS final rule (89 FR 98481 through 98483).

Impact of Policy Provision: We estimate a change of minus 810 submissions due to finalizing six new MVPs in this final rule. Multiplying the estimated change in submissions (-810) by the time per submission by labor category, we estimate a total change of -7,357.23 hours. This change of incorporates the following estimates: -3,307.23 hours for a computer system analyst (-810 submissions × 4.083 hr/submission (3 hr to submit data; 1 hr to review measure specifications, and 5 minutes (0.083 hr) to authorize or instruct the qualified registry or QCDR to submit quality measure data on their behalf), -1,620 hours for medical and health service managers (-810 submissions × 2 hr/submission), -810 hours for LPNs (-810 submissions × 1 hr/submission), -810 hours for billing clerks (-810 submissions × 1 hr/submission), and -810 hours for physicians (-810 submissions × 1 hr/submission). We estimate an annual change of - $901,575.18 [(-3,307.23 hr × $107.66/hr = -$356,056.38 for computer systems analysts) + (-1,620 hr × $132.44/hr = -$214,552.80 for medical and health service managers) + (-810 hr × $61.68/hr = -$49,960.80 for LPNs) + (-810 hr × $47.60/hr = -$38,556.00 for billing clerks) + (- 810 hr × $299.32/hr = -$242,499.20 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of +1,209 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (+1,209) by the time per submission identified in the preceding paragraph by labor category, we estimate a total change of +10,981.35 hours. This change incorporates the following estimates: 4,936.347 hours for computer system analysts (+1,209 submissions × 4.083 hr/submission), 2,418 hours for medical and health service managers (+1,209 submissions × 2 hr/submission), 1,209 hours for LPNs (+1,209 submissions × 1 hr/submission), 1,209 hours for billing clerks (+1,209 submissions × 1 hr/submission), and 1,209 hours for physicians (+1,209 submissions × 1 hr/submission). We estimate an annual change of +$1,345,684.44 [(+4,936.347 hr × $107.66/hr = $531,447.12 for computer system analysts) + (+2,418 hr × $132.44/hr = $320,239.92 for medical and health service managers) + (+1,209 hr × $61.68/hr = $74,571.12 for LPNs) + (+1,209 hr × $47.60/hr = $57,548.40 for billing clerks) + (+1,209 hr × $299.32/hr = $361,877.88 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and newly available data will result in a change of +399 submissions (-810 submissions due to policy provisions + 1,209 submissions due to updated data), an annual burden change of +3,624 hours (-7,357.23 hr due to policy provisions + 10,981.35 hr due to updated data, rounded to the hour) at a cost of +$444,109 (-$901,575.18 due to policy provisions + $1,345,684.44 due to updated data, rounded to the dollar). We estimate a total of 17,407 traditional MIPS submissions under the MIPS CQM/QCDR measure collection types for the CY 2026 performance period/2028 MIPS payment year (11,266 individual clinicians + 6,132 groups + 9 non-Shared Savings Program ACO APM Entities). We did not receive public comments on our burden estimates and assumptions, and therefore, we are finalizing our burden estimates as proposed.

(5) Traditional MIPS Quality Data Submission: eCQM Collection Type

The following changes, as presented in the CY 2026 PFS proposed rule (90 FR 32788), will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

These estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians, groups, and non-Shared Savings Program ACO APM Entities. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 79441

through 79442) and the CY 2025 PFS final rule (89 FR 98483 through 98485). All estimates encompass time to review measure specifications unless otherwise noted. All changes to submissions as described in this section are relative to our currently approved estimate of 27,179 submissions detailed in the CY 2025 PFS final rule (89 FR 98483 through 98485).

Impact of Policy Provisions: We estimate a change of -1,114 submissions due to finalizing six new MVPs in this final rule. Multiplying the estimated change in submissions by the time per submission by labor category, we estimate a total change of -8,912 hours. This change incorporates the following estimates: -3,342 hours for computer system analysts (-1,114 submissions × 3 hr/submission (2 hr to submit data file and 1 hr to review measure specifications)), -2,228 hours for medical and health service managers (-1,114 submissions × 2 hr/submission), -1,114 hours for LPNs (-1,114 submissions × 1 hr/submission), -1,114 hours for billing clerks (-1,114 submissions × 1 hr/submission), and -1,114 hours for physicians (-1,114 submissions × 1 hr/submission). We estimate an annual change of -$1,110,056.44 [(-3,342 hr × $107.66/hr = -$359,799.72 for computer system analysts) + (-2,228 hr × $132.44/hr = - $295,076.32 for medical and health service managers) + (-1,114 hr × $61.68/hr = -$68,711.52 for LPNs) + (-1,114 hr × $47.60/hr = -$53,026.40 for billing clerks) + (-1,114 hr × $299.32/hr = -$333,442.48 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of -2,129 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (-2,129) by the time per submission identified in the preceding paragraph by labor category, we estimate a total change of -17,032 hours. This change incorporates the following estimates: - 6,387 hours for computer system analysts (-2,129 submissions × 3 hr/submission), -4,258 hours for medical and health service managers (-2,129 submissions × 2 hr/submission), -2,129 hours for LPNs (-2,129 submissions × 1 hr/submission), -2,129 hours for billing clerks (-2,129 submissions × 1 hr/submission), and -2,129 hours for physicians (-2,129 submissions × 1 hr/submission). We estimate an annual change of -$2,121,463.34 [(-6,387 hr × $107.66/hr = - $687,624.42 for computer system analysts) + (-4,258 hr × $132.44/hr = - $563,929.52 for medical and health service managers) + (-2,129 hr × $61.68/hr = -$131,316.72 for LPNs) + (-2,129 hr × $47.60/hr = -$101,340.40 for billing clerks) + (-2,129 hr × $299.32/hr = -$637,252.28 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and the availability of updated data will result in a change of -3,243 submissions (-1,114 due to policy provisions + -2,129 due to updated data), an annual burden change of -25,944 hours (-8,912 hr due to policy provisions + -17,032 hr due to updated data) at a cost of -$3,231,520 (-$1,110,056.44 due to policy provisions + - $2,121,463.34 due to updated data, rounded to the dollar). We estimate a total of 23,936 traditional MIPS submissions under the eCQM collection type for the CY 2026 performance period/2028 MIPS payment year (18,282 individual clinicians + 5,647 groups + 7 non-Shared Savings Program ACO APM Entities). We did not receive public comments on our burden estimates or assumptions, and therefore our finalizing our estimates as proposed.

(6) ICRs Regarding Burden for MVP Reporting and Registration

The following changes, as presented in the CY 2026 PFS proposed rule (90 FR 32788 through 32791), will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 PFS final rule (86 FR 65590 through 65592), CY 2023 PFS final rule (87 FR 70155), CY 2024 PFS final rule (88 FR 79443), and CY 2025 PFS final rule (89 FR 98487) for our previously finalized burden assumptions and requirements for submitting quality performance category data for the MVP reporting option.

We refer readers to Appendix 3: MVP Inventory of this final rule for the updated format of the MVP tables. We do not anticipate that the new stratified update to the MVP format will affect the reporting burden, as it does not alter the composition of an MVP and does not affect the general minimum reporting requirements for each MVP.

In section IV.A.4.a. of this final rule, we are finalizing our proposal to update the MVP inventory in line with the MVP development criteria (85 FR 84849 through 84854). We are also finalizing our proposal to add six new MVPs to the MVP inventory for the CY 2026 performance period/2028 MIPS payment year.

In the CY 2025 PFS final rule (89 FR 98485 and 98486), we estimated that 10 percent of MIPS eligible clinicians from the CY 2022 performance period/2024 MIPS payment year will move from traditional MIPS reporting to MVP reporting for the CY 2025 performance period/2027 MIPS payment year. For details on prior approaches to estimating MVP reporting, we refer readers to the CY 2022 PFS final rule (86 FR 65588 through 65590), CY 2023 PFS final rule (87 FR 70155 and 70156), and CY 2024 PFS final rule (88 FR 79443 and 79444).

To estimate MVP submissions for the CY 2026 performance period/2028 MIPS payment year, we calculated the average quality measure submission rate for each of the new MVPs finalized in this final rule for the CY 2026 performance period/2028 MIPS payment year. For these analyses, we assessed measure submissions in the CY 2023 performance period/2025 MIPS payment year for clinicians with relevant clinical specialties for each MVP. We considered quality reporting trends from all quality performance category reporting options (traditional MIPS, MVPs, and the APP), by clinicians, groups, subgroups, and non-Shared Savings Program ACO APM Entities. The total of these average quality measure submissions for all the MVPs finalized as proposed was equivalent to about 4 percent of the total quality performance category submissions in the CY 2023 performance period/2025 MIPS payment year. Adding this incremental change of 4 percentage points to the existing estimate of 10 percent for MVPs established in the CY 2025 PFS final rule (89 FR 98485 and 98486), we estimated that MVP reporting will account for 14 percent of MIPS quality performance category submissions for the CY 2026 performance period/2028 MIPS payment year.

Continuing our approach from the CY 2022 PFS final rule (86 FR 65589 and 65590), CY 2023 PFS final rule (87 FR 70155 and 701566), CY 2024 PFS final rule (88 FR 79443 and 79444), and CY 2025 PFS final rule (89 FR 98486), we assumed that number of MVP registrations will equal our estimated MVP quality submissions.

(a) Burden for MVP Registration: Individuals, Groups, Subgroups, and APM Entities

The following changes, as presented in the CY 2026 PFS proposed rule (90 FR 32789), will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

In section IV.A.3.a. of this final rule, we are finalizing our proposal to add a new self-attestation requirement to the MVP registration process requiring each group to attest whether it is either a single-

specialty group or multispecialty group meeting the requirements of a small practice. We believe the associated impact of this provision will be minimal, and that this provision will not require the burden per registration to exceed the currently approved estimate of 15 minutes per registration. Therefore, we did not propose to revise the burden per MVP registration under OMB control number 0938-1314 (CMS-10621), and are not making any changes to the subgroup registration process under this control number. We refer readers to section IV.A.3.a. of this final rule for additional details on the MVP registration self-attestation requirement.

As described in section V.B.5.c.(6). of this final rule, we estimate that approximately 14 percent of the clinicians that participate in MIPS quality performance category reporting will submit data for the measures and activities in an MVP. For the CY 2026 performance period/2028 MIPS payment year, we assume that the total number of individual clinicians, groups, non-Shared Savings Program ACO APM Entities, and subgroups that will complete the MVP registration process is 8,110. All changes to the MVP registrations described below are relative to our currently approved estimate of 6,285 registrations detailed in the CY 2025 PFS final rule (89 FR 98486 and 98487).

We estimate that the finalized addition of six new MVPs will result in an increase of 2,312 MVP registrations. Using the currently approved estimate of 0.25/hr per registration, we estimate an annual burden change of +578.00 hours (+2,312 registrations × 0.25 hr/registration) at a cost of +$62,227.48 (+578 hr × $107.66/hr for a computer system analyst or equivalent). Additionally, we estimate that the availability of updated data will result in a change of -487 registrations. Using the currently approved estimate of 0.25 hr/registration, we estimate an annual change of -121.75 hours (-487 registrations × 0.25 hr/registration) at a cost of -$13,107.61 (-121.75 hr × $107.66/hr for a computer system analyst or equivalent) due to the availability of updated data.

Taken together, we estimate that the anticipated changes due to policy provisions and the availability of updated data will result in a change of +1,825 registrations (2,312 registrations due to policy provisions + -487 registrations due to updated data), an annual burden change of +456 hr (578.00 hr due to policy provisions + -121.75 hr due to updated data, rounded to the hour) at a cost of +$49,120 (+$62,227.48 due to policy provisions + -$13,107.61 due to updated data, rounded to the dollar). We

estimate a total of 8,110 MVP registrations for the CY 2026 performance period/2028 MIPS payment year.

We summarized comments received about the self-attestation proposal in section XX of this final rule and provided responses. We did not receive any comments about these on our burden estimates, and are finalizing the requirements and burden estimates as proposed.

(b) Burden for Subgroup Registration

In the CY 2026 PFS proposed rule (90 FR 32789), we did not propose to revise burden for subgroup registration for the CY 2026 performance period/2028 MIPS payment year. We previously finalized a requirement for subgroup reporting for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). In section IV.A.3.a.(3) of this final rule, we are finalizing our proposal to update the MVP group registration process to add the self-attestation process for groups. If a group does not self-attest as a single specialty group or a multispecialty group meeting the requirements of a small practice during MVP registration, clinicians in the group cannot register as a group. Clinicians in such groups could register as subgroups to participate in MVP reporting. However, we did not propose to revise our subgroups' burden estimates because we are operationalizing previously finalized policies that will not impact the utilization of subgroups by groups and hence, will not change the way groups choose to organize clinicians in subgroups.

Additionally, we are finalizing our proposal to maintain the MVP group reporting option for multispecialty groups with a small practice designation in section IV.A.3.a.(3) of this final rule. Maintaining the MVP group reporting option will not impact the currently approved burden for subgroup registration because it will not change any requirements related to subgroup registration. As future performance year data becomes available to reflect subgroup reporting trends amid revisions to the MVP inventory, we will evaluate changes to our currently approved burden estimate under OMB control number 0938–1314 (CMS–10621).

(c) Burden for MVP Quality Performance Category Submission

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). For prior discussions of

our related burden estimates, please see the CY 2022 PFS final rule (86 FR 65590 through 65592), CY 2023 PFS final rule (87 FR 70157 through 70159), CY 2024 PFS final rule (88 FR 79444 through 79446), and CY 2025 PFS final rule (89 FR 98487 through 98490).

The following changes as proposed in the CY 2026 PFS proposed rule (90 FR 32790) will be submitted to OMB for approval under control number 0938-1314 (CMS-10621), relative to the currently approved burden estimates detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

We estimate a change to the number of annual MVP quality performance category submissions per collection type from our currently approved burden estimates, beginning with the CY 2026 performance period/2028 MIPS payment year. These estimates include the figures detailed in section V.B.5.c.(1)(e) of this final rule plus our currently approved estimate of 20 subgroup submissions (split evenly across the eCQM and MIPS CQM/QCDR measure collection types). These estimates aggregate individual clinician, group, subgroup, and non-Shared Savings Program ACO APM Entity submissions. All estimates encompass time to review measure specifications unless otherwise noted.

(i) Medicare Part B Claims Measure Collection Type

All estimates below presume the maximum submission time. All changes to the estimated number of quality performance category submissions as described in this section are relative to our currently approved estimate of 1,355 submissions detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

Impact of Policy Provisions: We estimate a change of +388 submissions due to the six new MVPs finalized in this final rule. Multiplying the estimated change in submissions (+388) by the time per submission by labor category, we estimate a total change of +3,662.72 hours. This change incorporates the following estimates: 2,118.48 hours for computer system analysts (+388 submissions × 5.46 hr/submission (4.8 hr to submit data + 0.66 hr to review measure specifications), 776 hours for medical and health service managers (+388 submissions × 2 hr/submission), 256.08 hours for LPNs (+388 submissions × 0.66 hr/submission), 256.08 hours for billing clerks (+388 submissions × 0.66 hr/submission), and 256.08 hours for physicians (+388 submissions × 0.66 hr/submission). We estimate an annual change of +$435,483.29 [(2,118.48 hr × $107.66/hr = $228,075.56 for computer system analysts) + (776 hr × $132.44/hr = $102,773.44 for medical and health service managers) + (256.08 hr ×

$61.68/hr = $15,795.01 for LPNs) + (256.08 hr × $47.60/hr = $12,189.41 for billing clerks) + (256.08 hr × $299.32/hr = $76,649.87 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of -384 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (-384) by the time per submission by labor category, we estimate a total change of -3,624.96 hours. This change incorporates the following estimates, and applies the annual time per labor category identified in the preceding paragraph: -2,096.64 hours for computer system analysts (-384 submissions × 5.46 hr/submission), -768 hours for medical and health service managers (-384 submissions × 2 hr/submission), -253.44 hours for LPNs (-384 submissions × 0.66 hr/submission), -253.44 hours for billing clerks (-384 submissions × 0.66 hr/submission), and -253.44 hours for physicians (-384 submissions × 0.66 hr/submission). We estimate an annual change of -$430,993.76 [(-2,096.64 hr × $107.66/hr = -$225,724.26 for computer system analysts) + (-768 hr × $132.44/hr = -$101,713.92 for medical and health service managers) + (-253.44 hr × $61.68/hr = -$15,632.18 for LPNs) + (-253.44 hr × $47.60/hr = -$12,063.74 for billing clerks) + (-253.44 hr × $299.32/hr = -$75,859.66 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and newly available data will result in a change of +4 submission (+388 submissions due to policy provisions + -384 submissions due to updated data), an annual burden change of +38 hours (3,662.72 hr due to policy provisions + -3,624.96 hr due to updated data, rounded to the hour) at a cost of +$4,490 ($435,483.29 due to policy provisions + -430,993.76 due to updated data, rounded to the dollar). We estimate a total of 1,359 MVP submissions under the Medicare Part B claims measure collection type for the CY 2026 performance period/2028 MIPS payment year. We did not receive public comments on our burden estimates and assumptions for this collection type, and therefore, we are finalizing our burden estimates as proposed.

(ii) MIPS CQM/QCDR Measure Collection Type

All changes to the estimated number of quality performance category submissions described later in this section are relative to our currently approved estimate of 1,900 submissions detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

Impact of Policy Provisions: We estimate a change of +810 submissions due to the six new MVPs finalized in this final rule. Multiplying the estimated change in submissions (+810) by the time per submission by labor category, we estimate a total change of +4,835.70 hours. All estimates encompass time to review measure specifications unless otherwise noted. This change incorporates the following estimates: 2,154.60 hours for computer system analysts (+810 submissions × 2.66 hr/submission (2 hr to submit data and 0.66 hr to review measure specifications)), 1,077.30 hours for medical and health service managers (+810 submissions × 1.33 hr/submission), 534.60 hours for LPNs (+810 submissions × 0.66 hr/submission), 534.60 hours for billing clerks (+810 submissions × 0.66 hr/submission), and 534.60 hours for physicians (+810 submissions × 0.66 hr/submission). We estimate an annual change of $593,079.41 [(2,154.60 hr × $107.66/hr = $231,964.24 for computer system analysts) + (1,077.30 hr × $132.44/hr = $142,677.61 for medical and health service managers) + (534.60 hr × $61.68/hr = $32,974.13 for LPNs) + (534.60 hr × $47.60/hr = $25,446.96 for billing clerks) + (534.60 hr × $299.32/hr = $160,016.47 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of +134 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (+134) by the time per submission by labor category, we estimate a total change of +799.98 hours. This change incorporates the following estimates, and applies the annual time per labor category identified in the preceding paragraph: +356.44 hours for computer system analysts (+134 submissions × 2.66 hr/submission), 178.22 hours for medical and health service managers (+134 submissions × 1.33 hr/submission), 88.44 hours for LPNs (+134 submissions × 0.66 hr/submission), 88.44 hours for billing clerks (+134 submissions × 0.66 hr/submission), and 88.44 hours for physicians (+134 submissions × 0.66 hr/submission). We estimate an annual change of $98,114.37 [(356.44 hr × $107.66/hr = $38,374.33 for computer system analysts) + (178.22 hr × $132.44/hr = $23,603.46 for medical and health service managers) + (88.44 hr × $61.68/hr = $5,454.98 for LPNs) + (88.44 hr × $47.60/hr = $4,209.74 for billing clerks) + (88.44 hr × $299.32/hr = $26,471.86 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and newly available data will result in a change of +944 submissions (810 due to policy provisions + 134 due to updated data), an annual burden change of 5,636 hours (4,835.70 hr due to policy

provisions + 799.98 hr due to updated data, rounded to the hour) at a cost of +$691,194 ($593,079.41 due to policy provisions + 98,114.37 due to updated data, rounded to the dollar). We estimate a total of 2,844 MVP submissions under the MIPS CQM/QCDR measure collection types for the CY 2026 performance period/2028 MIPS payment year (10 subgroups + 1,834 individuals + 999 groups + 1 non-Shared Savings Program APM ACO entity).

We did not receive public comments on our burden estimates and assumptions for this collection type, and therefore, we are finalizing our burden estimates as proposed.

(iii) eCQM Collection Type

All changes to the estimated number of quality performance category submissions as described in this section are relative to our currently approved estimate of 3,030 submissions detailed in the CY 2025 PFS final rule (89 FR 98487 through 98490).

Impact of Policy Provisions: We estimate a change of +1,114 submissions due to the six new MVPs finalized in this final rule. Multiplying the estimated change in submissions (+1,114) by the time per submission by labor category, we estimate a total change of +5,904.20 hours. All estimates incorporate time to review measure specifications unless otherwise noted. This change incorporates the following estimates: 2,216.86 hr for computer system analysts (+1,114 submissions × 1.99 hr/submission (1.33 hr to submit data file and 0.66 hr to review measure specifications)), 1,481.62 hr for medical and health service managers (+1,114 submissions × 1.33 hr/submission), 735.24 hr for LPNs (+1,114 submissions × 0.66 hr/submission), 735.24 hr for billing clerks (+1,114 submissions × 0.66 hr/submission), and 735.24 hr for physicians (1,114 submissions × 0.66 hr/submission). We estimate an annual change of +$735,311.96 [(2,216.86 hr × $107.66/hr = $238,667.15 for computer system analysts) + (1,481.62 hr × $132.44/hr = $196,225.75 for medical and health service managers) + 735.24 hr × $61.68/hr = $45,349.60 for LPNs) + (735.24 hr × $47.60/hr = $34,997.42 for billing clerks) + (735.24 hr × $299.32/hr = $220,072.04 for physicians)].

Impact of Updated Data: Additionally, we estimate a change of -237 submissions due to the availability of updated data and assumptions. Multiplying the estimated change in submissions (-237) by the time per submission by labor category, we estimate a total change of -1,256.10 hours. This change incorporates the following estimates, and applies the annual time per labor category identified in the

preceding paragraph: -471.63 hr for computer system analysts (-237 submissions × 1.99 hr/submission) + -315.21 hr for medical and health service managers (- 237 submissions × 1.33 hr/submission) + -156.42 hr for LPNs (-237 submissions × 0.66 hr/submission) +-156.42 hr for billing clerks (-237 submissions × 0.66 hr/submission) + -156.42 hr for physicians (-237 submissions × 0.66 hr/submission). We estimate an annual change of -$156,435.31 [(-471.63 hr × $107.66/hr = -$50,775.69 for computer systems analysts) + (-315.21 hr × $132.44/hr = -$41,746.41 for medical and health service managers) + (-156.42 hr × $61.68/hr = -$9,647.99 for LPNs) + (-156.42 hr × $47.60/hr = -$7,445.59 for billing clerks) + (- 156.42 hr × $299.32/hr = -$46,819.63 for physicians)].

Total Impact: Taken together, we estimate that the changes in submissions due to policy provisions and newly available data will result in a change of +877 submissions (1,114 due to policy provisions + -237 due to updated data), an annual burden change of +4,648 hours (5,904.20 hr due to policy provisions + -1,256.10 hr due to updated data, rounded to the hour) at a cost of -$578,877 ($735,311.96 due to policy provisions + -$156,435.31 due to updated data, rounded to the hour). We estimate a total of 3,907 MVP submissions using the eCQM collection type for the CY 2026 performance period/2028 MIPS payment year (10 subgroups + 2,977 individuals + 919 groups + 1 non-Shared Savings Program APM ACO entity).

We did not receive public comments on our burden estimates, and therefore, we are finalizing our burden estimates as proposed.

(iv) Summation of Medicare Part B Claims Measure, MIPS CQM/QCDR Measure, and eCQM Collection Types

Across the quality performance category collection types for MVPs, we estimate that policy provisions will result in a total change of +2,312 submissions (388 Medicare Part B claims measure submissions + 810 MIPS CQM/QCDR measure submissions + 1,114 eCQM submissions), an annual burden change of +14,402.62 hours (3,662.72 hr for Medicare Part B claims measure submissions + 4,835.70 hr for MIPS CQM/QCDR measure submissions + 5,904.20 hr for eCQM submissions) at a cost of +$1,763,874.66 ($435,483.29 for Medicare Part B claims measure submissions + $593,079.41 for MIPS CQM/QCDR measure submissions + $735,311.96 for eCQM submissions).

Additionally, we estimate that updated data and assumption will result in a total change of -487 submissions (-384 Medicare Part B claims measure submissions + 134 MIPS CQM/QCDR measure submissions + -237 eCQM submissions), an annual burden change of -4,081.08 hours (-3,624.96 hr for Medicare Part B claims measure submissions + 799.98 hr for MIPS CQM/QCDR measure submissions + -1,256.10 hr for eCQM submissions) at a cost of - $489,314.70 (-$430,993.76 for Medicare Part B claims measure submissions + $98,114.37 for MIPS CQM/QCDR measure submissions +-$156,435.31 for eCQM submissions).

Taken together, we estimate that the change in submissions due to finalized policy provisions and newly available data will result in a change of +1,825 submissions (+2,312 submissions due to policy provisions + -487 submissions due to updated data), an annual burden change of +10,322 hours (+14,402.62 hr due to policy provisions + -4,081.08 hr due to updated data, rounded to the hour) at a cost of +$1,274,560 (+$1,763,874.66 due to policy provisions + -$489,314.70 due to updated data, rounded to the dollar). We estimate a total of 8,110 MVP submissions under the Medicare Part B claims measure, MIPS CQM/QCDR measure, and eCQM collection types for the CY 2026 performance period/2028 MIPS payment year (20 subgroups + 6,170 individuals +1,918 groups + 2 non-Shared Savings Program ACO APM entities).

We did not receive public comments on our burden estimates and assumptions, and therefore, we are finalizing our burden estimates as proposed.

(7) Beneficiary Responses to CAHPS for MIPS Survey

In section IV.B.4.a.(5) of this final rule, we are finalizing our proposal to update the CAHPS for MIPS Survey measure by changing from a mail-web protocol to a web-mail-phone protocol. As we were unable to estimate the incremental change in submissions above our currently approved estimates, we did not propose to change our currently approved estimates under OMB control number 0938-1222 (CMS-10450) (90 FR 32791 and 32792). We proposed to continue our currently approved estimate of response time per survey of 0.2183 hours (13.1 minutes), as we did not propose revisions to the survey questions. We did not receive public comments on our burden assumptions.

(8) Group Registration for CAHPS for MIPS Survey

In section IV.B.4.a.(5) of this final rule, we are finalizing our proposal to update the CAHPS for MIPS Survey measure by changing from a mail-web protocol to a web-mail-phone protocol. We do not anticipate that the provision will affect the number of groups registering for the CAHPS for MIPS Survey, nor will it affect the time to complete each group registration. In the CY 2026 PFS proposed rule (90 FR 32792), we did not propose changes to the requirements and burden estimates currently approved by OMB under control number 0938-1222 (CMS-10450). We did not receive public comments on our burden assumptions.

d. ICRs Regarding Reporting the Promoting Interoperability Performance Category

(1) Background

We refer readers to § 414.1375 for our previously established policies regarding reporting for the Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and §§ 414.1380(b)(4) and 414.1365(d)(3)(iv) for Promoting Interoperability performance category scoring. For historic assumptions on reporting requirements for the Promoting Interoperability performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79449 through 79451). As identified in section V.B.4., we do not estimate MIPS reporting burden due to requirements of the Shared Savings Program in the collection of information pages.

(2) Submitting Promoting Interoperability Data

In the following paragraphs, we outline the policy changes to the MIPS Promoting Interoperability performance category reporting requirements finalized in section IV.A.4.d.(4) of this final rule and our assumptions as to why such policies do not affect burden. For the first three policies finalized in this final rule, there are similar policies for the Medicare Promoting Interoperability Program in the Fiscal Year (FY) 2026 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Systems (IPPS/LTCH PPS) final rule (90 FR 37045 through 37056). Our burden assumptions for policies affecting the MIPS Promoting Interoperability performance category are consistent with the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18414 and 18415) and FY 2026 IPPS/LTCH PPS final rule (90 FR 37199).

First, beginning with the CY 2026 performance period/2028 MIPS payment year we are finalizing our proposal to modify the Security Risk Analysis measure to require MIPS eligible clinicians to submit a second attestation ("Yes" or "No") to having conducted security risk management activities as required under the HIPAA Security Rule implementation specification for risk management (codified at 45 CFR 164.308(a)(1)(ii)(B)). This attestation is in addition to the current requirement under the measure for MIPS eligible clinicians to attest "Yes" to having conducted or reviewed a security risk analysis as required under the HIPAA Security Rule. In the CY 2026 PFS proposed rule (90 FR 32792), we did not propose to update the currently approved time per MIPS Promoting Interoperability performance category submission due to the additional attestation, as we believe the currently approved burden of 2.7 hours per MIPS Promoting Interoperability performance category submission is sufficient to absorb the negligible effort of the additional attestation included as a component of the Security Risk Analysis measure.

Second, beginning with the CY 2026 performance period/2028 MIPS payment year, we are finalizing our proposal to modify the High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide measure by specifying that MIPS eligible clinicians use the version of the SAFER Guides published in January 2025. In the CY 2026 PFS proposed rule (90 FR 32792), we did not propose to revise our burden estimates because the modification of the measure does not alter the core requirement to attest "Yes" or "No."

Third, beginning with the CY 2026 performance period/2028 MIPS payment year, we are finalizing our proposal to establish the new optional bonus measure Public Health Reporting under Trusted Exchange Framework and Common Agreement (TEFCA). We did not propose to update our burden estimates in the CY 2026 PFS proposed rule (90 FR 32792) because the measure submission is optional and we cannot predict which MIPS eligible clinicians will elect to report this measure and how they will participate in MIPS (individual, group, virtual group, subgroup, or APM Entity (excluding Shared Savings Program Accountable Care Organizations (ACOs)) level). For further discussion regarding the three aforementioned policies, we refer readers to section IV.A.4.d.(4) of this final rule.

In sections IV.A.4.d.(4)(f) and IV.A.4.d.(4)(g) of this final rule, we are finalizing the following: (1) establish a measure suppression policy for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program; and (2) suppress the Electronic Case Reporting

measure for the CY 2025 performance period/2027 MIPS payment year for the MIPS Promoting Interoperability performance category and the EHR reporting period in CY 2025 for the Medicare Promoting Interoperability Program. For further discussion regarding such policies, we refer readers to sections IV.A.4.d.(4)(f) and IV.A.4.d.(4)(g) of this final rule. The suppression of a measure only pertains to a measure not being assessed for performance, and thus, MIPS eligible clinicians, eligible hospitals, and CAHs will continue to be required to report the measure. In the CY 2026 PFS proposed rule (90 FR 32792), we did not propose to revise our burden estimates because the measure suppression policy does not impact reporting requirements of the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

We summarized the comments received regarding the aforementioned proposals in section XX of this final rule. We did not receive public comment on the burden assumptions for submitting Promoting Interoperability data, and are finalizing our requirements and burden estimates as proposed.

Independent of the aforementioned policies, we proposed to update the currently approved burden estimates for the number of total submissions for the MIPS Promoting Interoperability performance category due to the availability of updated data from the CY 2023 performance period/2025 MIPS payment year (90 FR 32792). Additionally, we increased the time per MIPS Promoting Interoperability performance category submission by 30 seconds (0.083 hour) to account for the addition of the Electronic Prior Authorization measure under the Health Information Exchange objective for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year. Such measure was established in the CMS Interoperability and Prior Authorization final rule published in the **Federal Register** on February 8, 2024 (89 FR 8758). In this final rule, we do not outline the burden estimate updates in this collection of information section due to the burden estimates not being affected by the policy provisions in this final rule. The applicable burden changes will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

e. ICRs Regarding Reporting for the Improvement Activities Performance Category

We refer readers to §§ 414.1355 and 414.1365(c)(3) for our previously established policies regarding reporting for the improvement activities performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1360 for data submission requirements, and

§§ 414.1380(b)(3) and 414.1365(d)(3)(iii) for improvement activities performance category scoring. For historic assumptions on reporting requirements for the improvement activities performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79454 and 79455).

In section IV.A.4.d.(3)(b) of this final rule, we are finalizing our proposed changes to the Improvement Activities Inventory for the CY 2026 performance period/2028 MIPS payment year and future years. Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70211), the CY 2024 PFS final rule (88 FR 79519), and the CY 2025 PFS final rule (89 FR 98492), we believe clinicians performing improvement activities will continue to perform the same activities because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified via rulemaking (82 FR 54175). We did not receive public comment on these burden assumptions.

We refer readers to section VII.I.5.e.(2)(a) of this final rule for additional discussion. Independent of these policies, we are updating the number of submissions due to the availability of updated submission data from the CY 2023 performance period/2025 MIPS payment year. While not scored in this rule, the non-policy changes will be submitted to OMB for approval under control number 0938-1314 (CMS-10621).

f. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938-1197; CMS-1500 and CMS-1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by Compact Disc or hardcopy. The following policies finalized in section IV.A.4.d.(2) of this final rule will not result in the need to add or revise or delete any claims data fields: (1) modify the Total Per Capita Cost (TPCC) measure beginning in the CY 2026 performance period/2028 MIPS payment year; (2) update the operational list of care episode and patient condition groups and codes to reflect coding changes identified through annual maintenance of MIPS cost measures; and (3) adopt an informational-only feedback period of 2 years for new MIPS cost measures. Consequently, we are not making any changes under the aforementioned OMB control number.

C. Summary of the Annual Burden Estimates

Table D-A14 sets out the burden for the provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of this rule's provisions.

TABLE D-A14: THE ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	(65)	(260)	13	(3,380)	45.80	(154,804)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)	435	4	varies	77	Varies	1,894,286
§§ 414.1325, 414.1335, and 414.1365 Quality Payment Program	0938-1314 (CMS-10621)	57,803	65,913	Varies	(6,798)	Varies	(840,757)
§§ 414.1400 Quality Payment Program: CAHPS for MIPS Survey	0938-1222 (CMS-10450	10	10	+1	+10	107.66	+1,077
Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act	0938-TBD (CMS-10930)	6,500 Covered Entities or TPAs	26,000 Covered Entities or TPAs	8 Covered Entities or TPAs	208,000 Covered Entities or TPAs	Varies	23,195,120 Covered Entities or TPAs
TOTAL	n/a	64,683	91,667	varies	197,909	varies	22,698,711

VI. Regulatory Impact Analysis

A. Statement of Need

In this final rule, we finalized payment and policy changes under the Medicare PFS. Our proposed policies in this rulemaking specifically address: changes to the PFS; and other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program (MIPS and Advanced APMs); changes to payment policies for drugs and biologicals products paid under Medicare Part B, other changes to Medicare Part B payment policies for Rural Health Clinics and Federally Qualified Health Centers, and changes to the regulations associated with the Ambulance Fee Schedule. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Medicare Prescription Drug Inflation Rebate Program

Section III.I. of this final rule finalized regulations to implement provisions of the Inflation Reduction Act of 2022 (IRA) that establish the Medicare Prescription Drug Inflation Rebate Program. Sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A of the Social Security Act (the Act) by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower

inflation-adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a "Part B rebatable drug," in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B.

Section 11102 of the IRA added section 1860D-14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period that began on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug, which is calculated as set forth in section 1860D-14B(b)(2) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1860D-14B(b)(3) of the Act. Section 1860D-14B(g)(1)(A) of the Act defines a "Part D rebatable drug," in part, as a drug or biological described at section 1860D-14B(g)(1)(C) of the Act that is a "covered Part D drug" as that term is defined in section 1860D-2(e) of the Act. The definition of a Part D rebatable drug includes drugs approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act, drugs approved under an abbreviated new drug application under section 505(j) of the FD&C Act that meet certain sole source criteria described at sections 1860D-14B(g)(1)(C)(ii)(I) through (IV) of the Act, and biologicals licensed under section 351 of the Public Health Service Act, including biosimilars.

b. Quality Payment Program

This final rule is also necessary to make changes to the Quality Payment Program to move the program forward to focus more on measurement efforts, refine how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is a value-based payment program that includes two participation tracks: MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We continue to move the Quality Payment Program forward, including focusing more on alignment between the Merit-based Incentive Payment

System (MIPS) and Advanced Alternative Payment Models (APM) tracks of participation, alignment with broader CMS initiatives, and new options for clinicians to participate in more meaningful ways. We aim to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the MIPS and Advanced APMs for the CY 2026 performance period/2028 MIPS payment year.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

In section III.A.1. of this final rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021) (IIJA), which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter, refundable drug), we discuss two applications received for increased applicable percentage.

In section III.A.2 of this final rule, we discuss the calculation of manufacturer's Average Sales Price (ASP) related to price concessions and bona fide service fees (BFSFs). Regarding the proposals we made for price concessions, we finalized adding a definition of bundled arrangement at § 414.802 to specify how certain financial benefits, including rebates, discounts or other price concessions, are conditional upon certain requirements being met. We also finalized adding paragraphs at § 414.804(a)(2) to provide manufacturers with additional guidance on how to allocate discounts under bundled arrangements.

We also finalized several evidence requirements changes for BFSFs at § 414.804. Specifically, we finalized revisions at § 414.804(a)(5) that manufacturers are required to provide sufficient evidence that the BFSF is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug by providing documentation (such as a certification or warranty from the recipient of the fee). In addition, we finalized to revise § 414.804(a)(5) to add data submission requirements. Under this revision, manufacturers will be required to submit reasonable assumptions for calculations of the manufacturer's ASP, including documentation of the fair market value methodology for BFSF contracts.

In section III.A.3. of this final rule, we finalized that preparatory procedures for patient-specific cell or tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself. However, we are not finalizing the proposal to require manufacturers, beginning January 1, 2026 (that is, data reflecting sales beginning on that date), to include manufacturer-paid preparatory procedures for such procurement in the calculation of the manufacturer's ASP. Instead, we conclude that such payments may be treated as BFSFs when the four-part test at § 414.802 is satisfied.

b. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this final rule, we finalized changes to the furnishing of Advance Primary Care Management (APCM) services in RHCs and FQHCs. We finalized to adopt add-on codes for APCM that will facilitate billing for Behavioral Health Integration (BHI) and Psychiatric Collaborative Care Model (CoCM) services when RHCs and FQHCs are providing advanced primary care. We also finalized to require RHCs and FQHCs to report the individual codes that make up the CoCM HCPCS code, G0512. We also finalized to require RHCs and FQHCs to report the individual codes that make up the communications technology-based services (CTBS), HCPCS code G0071 as well. In addition, we finalized to revise § 405.2464(c) and (e) to reflect our proposal on payment of CoCM and CTBS services for RHCs and FQHCs. We also finalized to adopt services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs.

In section III.B.3. of this final rule, we finalized to adopt the definition "immediate availability" as including real-time audio and visual interactive telecommunications for the direct supervision permanently for all RHC and FQHC services. We also finalized, on a temporary basis, to facilitate payment for non-behavioral health visits furnished via telecommunication technology using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. RHCs and FQHCs will continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2026. We also finalized that, beginning October 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the

telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

c. Ambulatory Specialty Model (ASM)

In section III.C of this final rule, we discuss the finalized provisions of the mandatory alternative payment model called the Ambulatory Specialty Model (ASM) which would be tested under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries while reducing program expenditures.

Health care is becoming more fragmented as Medicare beneficiaries are increasingly seeing a greater number of specialists on a more regular basis. We believe there are opportunities to improve coordination between specialists and primary care providers (PCPs) and increase beneficiary engagement in care decisions, particularly with respect to preventing the onset and progression of chronic disease. ASM will test whether rewarding select specialists that furnish a high volume of services related to heart failure or low back pain based on measures of quality, cost, care coordination, and Promoting Interoperability results in enhanced quality of care and reduced costs through more effective upstream chronic condition management for ASM's targeted chronic conditions. We expect that a more targeted approach where clinicians are evaluated: (1) on a set of relevant performance measures they are required to report; and (2) among clinicians furnishing similar sets of services for similar chronic conditions, will produce scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement will also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. We believe this insight is necessary to support and incentivize accountable care, increasing beneficiary access to coordinated specialty care.

We believe that ASM's meaningful comparisons of performance to similar specialists furnishing a substantial volume of services related to ASM's targeted chronic conditions when matched with a

payment methodology that creates impactful Medicare Part B payment adjustments will encourage quality improvements in specialty care and meaningful engagement with primary care clinicians to both prevent and manage the onset of chronic conditions, all while achieving net savings to Medicare.

We refer readers to section III.C.1 of this final rule for more information on our research and rationale for ASM, as well as our finalized provisions.

d. Effects of Proposals Being Finalized Relating to the Medicare Diabetes Prevention Program Expanded Model

1. Effects on Beneficiaries

We proposed to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) address barriers related to weight collection requirements by clarifying that weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the completion of the MDPP session; (2) allow beneficiaries to self-report weight from a reasonable location outside of an in-person delivery site; (3) extend the flexibilities allowed during the PHE for COVID-19 through December 31, 2029; (4) test the addition of coverage of asynchronous, Online delivery of MDPP through December 31, 2029; (5) clarify that MDPP suppliers are not required to maintain In-person delivery capability through December 31, 2029; and (6) introduce a new Healthcare Common Procedure Coding System (HCPCS) G-code and payment for Online sessions.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 sessions using a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum.[473] CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence-based DPRP Standards, which are updated every 3 years. The 2024 CDC DPRP Standards replaced the 2021 CDC DPRP Standards in June 2024.[474]

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[473] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html*.

[474] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures*.

The CY 2021 PFS final rule allowed for increased virtual delivery of MDPP during the PHE for COVID-19 (85 FR 84830). Improvements to MDPP in the CY 2024 final rule included a simplified payment structure to allow for fee-for-service (FFS) payments for beneficiary attendance, while retaining the performance-based payments for diabetes risk reduction (that is, weight loss) (88 FR 79241) and an extension of PHE flexibilities to deliver some or all MDPP sessions via distance learning, until December 31, 2027 (88 FR 79241). Another PHE flexibility extended through the CY 2024 PFS final rule was for MDPP suppliers to obtain weight measurements for beneficiaries using one of the following options through December 31, 2027: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary (88 FR 79243). The CY 2025 PFS expanded this flexibility by allowing beneficiaries with the choice to submit one or two (2) photos for self-reporting weight for an MDPP Distance learning session (89 FR 98047). Finally, to align with 2024 CDC DPRP Standards, the CY 2025 PFS final rule (89 FR 98045) updated the MDPP definition of "Online" to align with the 2024 CDC DPRP definition for this delivery modality. However, while the CY 2025 PFS final rule updated the MDPP definition for Online, only In-person, Distance learning (synchronous), and In-person with a distance learning component remained accepted delivery modalities for MDPP in CY 2025.

We proposed to revise the definitions of "Extended flexibilities period" and "Online" and add definitions for three new terms for MDPP, including "Live Coach interaction," "Online delivery period," and "Online session." These changes will extend virtual delivery flexibilities through December 31, 2029, describe accepted delivery modes for MDPP by including Online (asynchronous) delivery, and further align MDPP terminology with CDC DPRP Standards. These proposed changes aim to remove access barriers for beneficiaries and provide MDPP suppliers with more delivery offerings in response to comments regarding the increasing demand for virtual participation options.

Through the CY 2026 PFS (90 FR 32593 through 32597), we proposed to clarify that weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within two (2) days of the completion of the MDPP session. Beneficiaries may also choose to report weight measurements according to the CY 2025 PFS policies regarding beneficiary

weight self-reported measurements and virtual weight collection (89 FR 98045), which allow beneficiaries to self-report their weights by providing one or 2 (two) date-stamped photo(s) or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Beneficiaries who participate in MDPP do not currently have the option to submit medical record data as proof of weight. This proposed change is in response to MDPP supplier feedback that the current weight collection requirements discourage individuals with mobility concerns from participating in MDPP due to risk of injury while self-reporting weight from home. For example, some beneficiaries may need to obtain weight at a medical office using a special scale (for example, wheelchair scale). This flexibility may promote safe and consistent collection of weight for MDPP sessions while encouraging model participation. After consideration of public comments indicating that the proposed 2 day timeframe was overly restrictive, we are finalizing the changes to the provision at § 410.79 (c)(1)(ii) to allow for weight measurements used to determine the achievement or maintenance of the required minimum weight loss to be based on weight documented in the beneficiary's medical record with an updated timeframe of five (5) calendar days, which provides sufficient flexibility while maintaining clear separation between sessions.

Additionally, we proposed to revise weight collection requirements for MDPP in response to comments regarding increased flexibility for MDPP beneficiaries who may be traveling or unable to obtain weight measurements at home. This change allows beneficiaries to self-report weight from a reasonable location outside of an In-person delivery site while maintaining program integrity through existing date-stamped photo requirements described at § 410.79(e)(3)(iii)(c) which state that the photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scaled on the date associated with the billable MDPP session. The current weight collection requirements state that beneficiaries self-report weight by submitting date-stamped photo(s) or video of the beneficiary’s weight on the scale with the beneficiary visible in their home. This limits beneficiaries from participating by reporting weight from other reasonable locations outside of an in-person delivery site or home, such as a medical office, or hotel if the beneficiary is on vacation but otherwise able to participate in MDPP sessions. This proposed change is expected to remove barriers to weight collection and provide flexibilities that may increase session attendance.

We proposed to test the addition of coverage of an asynchronous, Online delivery modality during the Online delivery period (until December 31, 2029). This change will allow virtual-only organizations to enroll in Medicare as MDPP suppliers, streamline the process to allow for greater delivery of Online sessions, and promote alignment with the 2024 CDC DPRP Standards, which support asynchronous delivery. To date, MDPP suppliers have commented that the exclusion of the asynchronous modality significantly limits program participation among Medicare beneficiaries. Advocacy group members pursued legislation that would require CMS to open the MDPP to suppliers of asynchronous, Online MDPP programs through the PREVENT DIABETES Act [H.R. 7856][475] in April 2024. Although this bill was not enacted into law, suppliers continue to encourage CMS to meet the demand for asynchronous delivery of MDPP. To facilitate the ability of MDPP suppliers to deliver the program through an asynchronous, Online delivery modality, we proposed to clarify that MDPP suppliers are not required to maintain the ability to deliver the program In-person during the Online delivery period. This will allow for virtual-only organizations to enroll in Medicare as MDPP suppliers and streamline the process to allow for greater asynchronous delivery. Additionally, beneficiary focus groups indicate that among beneficiaries who participate in MDPP via Distance learning or In-person with a distance learning component (hybrid), most expressed their satisfaction by citing the flexibility the choices provided when faced with challenges such as inclement weather or travel restrictions that made in-person participation difficult.[476] This extended flexibility is expected to promote beneficiary access to the Set of MDPP services, since suppliers may deliver the set of MDPP services to beneficiaries across State lines, reaching beneficiaries who do not live near an In-person delivery site. Upon further review of existing regulations, we have determined that current requirements for make-up sessions do not adequately address Online delivery. Make-up sessions for Online delivery were referenced in the CY 2026 PFS proposed rule (90 FR 32593) at § 410.79 (f)(2)(i)(C), which states the Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component) or fully asynchronously (that is, Online). Therefore, we are finalizing additional updates to ensure regulatory clarity for make-up sessions offered

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[475] H.R. 7856 (118th): PREVENT DIABETES Act, https://www.govtrack.us/congress/bills/118/hr7856/text.
[476] RTI International. Evaluation of the Medicare Diabetes Prevention Program. March 2025. https://www.cms.gov/priorities/innovation/data-and-reports/2025/mdpp-finalevalrpt.

through Online delivery by revising existing requirements at § 410.79(d)(1), which state "an MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person or distance learning delivery." We are revising this language to indicate that Online delivery is also an accepted delivery modality for make-up sessions by specifically stating that "an MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only be used in-person, distance learning, or Online delivery." We would like to reiterate that the Set of MDPP services, inclusive of make-up sessions, must be delivered to individual beneficiaries fully synchronously (that is, In-person, Distance learning, or In-person with a distance learning component) or fully asynchronously (that is, Online). Therefore, a supplier may not offer an Online make up session to a beneficiary who is participating in MDPP through In-person, Distance learning, or In-person with a distance learning component delivery.

We proposed edits throughout § 414.84 by revising paragraphs (b)(1) introductory text and (b)(2) introductory text to update language to include all accepted MDPP delivery modes for performance goals in which beneficiaries achieve weight loss milestones. We also proposed adding paragraph (c)(3) to describe the proposed payment for Online delivery, including the inclusion of a new HCPCS G-code for the Set of MDPP services delivered Online. Finally, we proposed redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5) respectively and revising the redesignated paragraph (c)(4)(ii) to include a payment rate for a core session or core maintenance session furnished Online during the Online delivery period.

Lastly, we proposed amending § 424.205(c)(10) to allow the minimum number of required MDPP core sessions and core maintenance sessions to be delivered Online during the Online delivery period; § 424.205(f)(2)(i) to include the Online delivery modality among acceptable session types for session documentation; and § 424.205(f)(5) to update requirements for achieving 5 and 9 percent weight loss measured in accordance with § 410.79(c)(ii). Overall, these modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date, feedback from existing MDPP suppliers, and feedback from beneficiary focus groups. The proposed changes are also in response to comments from interested parties made through public comments in response to prior

rulemaking. These proposed changes are aimed towards increasing access and participation in this prevention-focused program, empowering beneficiaries, and promoting further alignment between MDPP and the CDC DPRP Standards.

The policy changes proposed for MDPP in the CY 2026 PFS (90 FR 32593) are expected to have a significant impact on beneficiaries' access to MDPP services. Aligning with 2024 CDC DPRP Standards for MDPP delivery modes may help expand beneficiary access and increase the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers. Additionally, the proposed changes to weight collection requirements and the inclusion of Online delivery will increase flexibility for both MDPP suppliers and beneficiaries and may help increase access for beneficiaries who lack transportation or live in geographic areas without access to an In-person delivery site.

2. Effects on the Market

We anticipate that the policy changes proposed in this rulemaking are likely to result in a greater number of MDPP suppliers and increased beneficiary access to the Set of MDPP services. We anticipate that our proposal will result in the delayed onset and reduction of the incidence of diabetes among eligible Medicare beneficiaries.

As of May 2025, there are approximately 1,253 nationally recognized In-person organizations that are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes DPRP status.[477] However, only 330 (26 percent) of these eligible In-person organizations are participating in MDPP.[478] Aligning with CDC DPRP delivery modes, particularly allowing asynchronous, Online delivery, is expected to help increase recruitment of new DPRP organizations, MDPP suppliers, and beneficiaries.

3. Payment for MDPP Services

Regulations at § 414.84 specify that MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance targets related to MDPP beneficiary weight loss and attendance.

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[477]Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program Application. Registry of All Recognized Organizations. *https://dprp.cdc.gov/Registry*.

[478] *Medicare Provider Enrollment, Chain, and Ownership System (PECOS),* Centers for Medicare & Medicaid Services | CMS (.gov)*, accessed May 1, 2025).*

We anticipated that the inclusion of asynchronous, Online delivery will have minimal impact on total payment for MDPP services, as current performance payments for 5 percent weight loss achieved from baseline weight (G9880) and 9 percent weight loss achieved from baseline weight (G9881) will remain the same regardless of delivery modality for MDPP. For each beneficiary, MDPP suppliers must either bill claims with G9886, G9887, a combination of G9886 and G9887, or G9871. The proposed G9871 for behavioral counseling for diabetes prevention, online, 60 minutes ($18) is for the Set of MDPP services delivered Online, asynchronously. The existing G9886, behavioral counseling for diabetes prevention, in-person, group, 60 minutes, and G9887, behavioral counseling for diabetes prevention, distance learning, 60 minutes are delivered synchronously. Therefore, we proposed that for each MDPP beneficiary, suppliers may not bill for the Set of MDPP services that were delivered through a combination of synchronous and asynchronous delivery modalities, inclusive of make-up sessions. To evaluate the efficacy of the Online delivery modality during the Online Delivery Period, beneficiary outcomes from synchronous (that is, In-person, Distance learning, or In-person with a Distance learning component) delivery of the Set of MDPP services must be compared to beneficiary outcomes from asynchronous (that is, Online), therefore, these modalities must be delivered separately for individual beneficiaries in order to evaluate whether Online results, including weight loss, are similar to In-person and Distance learning delivery modalities.

The total maximum payment per beneficiary for MDPP for In-person or Distance learning delivery will remain unchanged by our proposals. The total maximum payment per beneficiary for Online delivery of MDPP will be $619.

4. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

Table D-B1 shows the estimated impact (in millions) on Medicare spending for allowing asynchronous, Online delivery of the MDPP benefit:

TABLE D-B1: ESTIMATED IMPACT (IN MILLIONS) ON MEDICARE SPENDING

	Year								
	2026	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**
Gross Medicare Impacts	-$1	-$4	-$7	-$9	-$11	-$11	-$11	-$10	-$8
Performance Payments	$6	$11	$2	$2	$0	$0	$0	$0	$0
Total Impact	$5	$6	-$5	-$7	-$11	-$11	-$11	-$10	-$8

(b) Assumptions/Notes

● While we proposed several changes to the existing MDPP expanded model for CY 2026, these changes should not lead to significantly different impacts on Medicare spending. The previous table provides projected impacts to Medicare fee for service spending resulting from allowing asynchronous, Online, delivery of MDPP without requiring providers to maintain an In-person delivery option.

● The assumed annual cost of diabetes from the initial certification of MDPP was trended forward using USPCC FFS PMPM spending assumptions included in the 2024 Trustees Report.

● Average per beneficiary MDPP payments for the asynchronous, Online delivery was assumed to be less than the In-person or Distance Learning benefit due to the reduced payment rate for session attendance. In 2025, the maximum total payment for completion of MDPP with weight loss is $795. The proposed maximum payment for the asynchronous, Online, delivery of MDPP is $619. Average per beneficiary MDPP payments were trended forward using a projected annual increase of 2.4 percent, consistent with the long-range CPI-U assumption included in the 2024 Trustees Report.

● The previous listed impact assumes that there are 15,000 new beneficiaries in 2026; 25,000 new beneficiaries in 2027; tapering off to 5,000 new beneficiaries in years 2028 and 2029. It is anticipated that the number of new beneficiaries in 2026 and 2027 may be higher due to pent up demand for the Online delivery modality. Additionally, it may take up to 90 days for approval of a Medicare enrollment application for those organizations newly enrolling as MDPP suppliers with an Online organization code, leading to lower uptake of the model in 2026 compared to 2027. There is a high degree of uncertainty with respect to the potential utilization of the asynchronous benefit. The CMS Office of Communications (OC) sends emails to a distribution list made up of potential MDPP participants twice every year. The emails contain a link to a website where more information relating to MDPP is available. OC reviews Medicare fee for service claims data to exclude beneficiaries that would be ineligible to participate in MDPP (ESRD patients or beneficiaries with a diabetes diagnosis) to develop the distribution list. In the last email distribution, approximately 11.8 million emails were sent. Of those receiving the email, about 86,000 recipients followed the link. With little information about the potential interest in the asynchronous, Online benefit from the supplier and beneficiary sides, utilization was assumed to be up to 20 percent in the first year and up to just over half of the number of email recipients who followed the email link during the 4 years of the asynchronous test.

● To evaluate the reduction in diabetes rates, the effectiveness of asynchronous, Online benefit is assumed to be equal to that of the in-person benefit. This assumption is revisited in the sensitivity analysis section.

(c) Sensitivity Analysis

Table D-B2 shows projected 10-year financial impacts (in millions) of delivering the asynchronous Online benefit from 2026 to 2029 at various levels of effectiveness with respect to the In-person benefit. It also provides the first year in which the accumulated savings are greater than the performance payments.

TABLE D-B2: 10-YEAR COST IMPACTS (IN MILLIONS) OF ONLINE DELIVERY OF MDPP SERVICES AND BREAK-EVEN POINT

Effectiveness Relative to In-Person	10-Year Impact	Break-Even Year
—100%	−$56	2029
75%	−$36	**2030**
50%	−$16	**2031**

As indicated in Table D-B2, asynchronous, Online delivery of MDPP services is estimated to produce savings over the next 10 years even when it is 50 percent as effective as the In-person delivery.

As for the Medicare Diabetes Prevention Program, given that we tried to align this final rule as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rule impacts only enrolled MDPP suppliers and eligible beneficiaries who have started MDPP or are interested in enrolling in MDPP.

We solicited comments on the regulatory impact analysis for this proposal.

We did not receive public comments on the regulatory impact analysis for this provision, and therefore, we are finalizing as proposed.

e. Medicare Shared Savings Program

In section III.F. of this final rule, we are finalizing modifications to the Shared Savings Program regulations to allow for timely improvements to program policies and operations. The changes to the Shared Savings Program include the following.

We are finalizing our proposed changes to limit participation in a one-sided model to an ACO's first agreement period under the BASIC track's glide path (if eligible), for a maximum of 5 performance years instead of 7 performance years. Under the policies being finalized, ACOs inexperienced with

performance-based risk Medicare ACO initiatives (defined at § 425.20) will progress more rapidly to higher levels of risk and potential reward under Level E of the BASIC track or the ENHANCED track (if eligible), compared to existing policies. These changes apply to agreement periods beginning on or after January 1, 2027.

We are also finalizing our proposed modifications to the Shared Savings Program eligibility and financial reconciliation requirements in connection with the statutory requirement that ACOs have at least 5,000 assigned Medicare FFS beneficiaries to: (1) require ACOs applying to enter a new agreement period beginning on or after January 1, 2027, to have at least 5,000 assigned beneficiaries in benchmark year (BY) 3, while allowing an ACO to have fewer than 5,000 assigned beneficiaries in BY1, BY2, or both; (2) establish safeguards to reduce the risk that ACOs owe shared losses payments, or are owed shared savings payments by the program, based on normal variation in beneficiary expenditures by (i) requiring that an ACO applying to enter a new agreement period that has fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, may only enter the BASIC track, and (ii) capping shared savings or shared losses at a lesser amount if an ACO, at any time during the agreement period, has fewer than 5,000 assigned beneficiaries in any of the three BYs; as well as (3) exclude ACOs that fall below 5,000 assigned beneficiaries in any benchmark year from being eligible to leverage existing policies that provide certain low revenue ACOs participating in the BASIC track with increased opportunities to share in savings.

We are finalizing our proposed changes to the Shared Savings Program's quality performance standard and other quality reporting requirements, including to: (1) revise the definition of a beneficiary eligible for Medicare CQMs at § 425.20 for performance year 2025 and subsequent performance years so that the population identified for reporting within the Medicare CQM collection type will have greater overlap with the beneficiaries that are assignable to an ACO; (2) update the APP Plus quality measure set for Shared Savings Program ACOs including the removal of Quality ID: 487 Screening for Social Drivers of Health; and (3) implement a web-mail-phone protocol and discontinue the mail-phone protocol for the CAHPS for MIPS Survey beginning with 2027. We are finalizing with modifications our proposal to remove the health equity adjustment applied to an ACO's quality score and to revise the terminology used to describe the health equity adjustment and other related terms; specifically, we are removing the health equity adjustment applied to an ACO's quality score beginning in performance year 2026 and we are

revising the terminology used to describe the health equity adjustment and other related terms for performance years 2023 through 2025.

We are finalizing our proposed changes to expand the application of the Shared Savings Program's quality and finance extreme and uncontrollable circumstances (EUC) policies to an ACO that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years.

We are finalizing our proposed changes to other programmatic areas, including: changes to Shared Savings Program eligibility requirements and change request procedures to: (1) require ACOs that experience certain ACO participant CHOWs outside of the change request cycle to update their certified ACO participant list to reflect such ACO participant's CHOW; and (2) require ACOs to submit changes which occur during the performance year to the ACO's SNF affiliate list, if a SNF affiliate undergoes a CHOW resulting in a new TIN. We are finalizing our proposed updates to the beneficiary assignment methodology to revise the definition of primary care services to align with payment policy changes and include, among other services for the purposes of beneficiary assignment, new behavioral health integration and psychiatric collaborative care model add-on services when these services are furnished with advanced primary care management services. We are finalizing our proposed changes to the Shared Savings Program's regulations specifying the financial benchmarking methodology applicable for agreement periods beginning on January 1, 2025, and in subsequent years, to rename the "health equity benchmark adjustment" (HEBA) the "population adjustment." Finally, we are finalizing our proposed changes to revise the Shared Savings Program's quality reporting monitoring policies.

f. Changes to the Regulations Associated with the Ambulance Fee Schedule

As outlined in section III.G. of this final rule, section 3203 of the American Relief Act of 2025 and most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons sets forth in those subsections through September 30, 2025. The ambulance extender provisions are enacted through legislation that is self-implementing. We proposed only to revise dates at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866, Regulatory Planning and Review (September 30, 1993), Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354); section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4); and Executive Order 13132, Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series).) Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners,

and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rulemaking will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rulemaking does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this rule; details the costs and benefits of this rulemaking; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this rule, we discussed

various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule. The relevant sections of this rulemaking describe significant alternatives we considered, if applicable.

C. Executive Order 14192, "Unleashing Prosperity Through Deregulation"

Executive Order 14192, titled "Unleashing Prosperity Through Deregulation" was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations."

D. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2025 with payment rates for CY 2026 using CY 2024 Medicare utilization. The payment impacts described in this rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

As required by section 1848(d)(1)(A) of the Act, beginning in CY 2026, there will be two separate conversion factors (CFs): one for items and services furnished by a qualifying APM

participant as defined in section 1833(z)(2) of the Act (referred to as the qualifying APM conversion factor) and another for other items and services (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year (or, for CY 2026, equal to the single conversion factor for CY 2025) multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. As specified by section 1848(d)(20) of the Act, the update to the qualifying APM conversion factor for CY 2026 is 0.75 percent while the update to the nonqualifying APM conversion factor for CY 2026 is 0.25 percent. To calculate the estimated CY 2026 PFS conversion factors, we took the CY 2025 conversion factor and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs, then multiplied by the qualifying APM and nonqualifying APM updates specified by section 1848(d)(20) of the Act, then applied the 1-year increase of 2.50 percent for CY 2026 established by statute. We estimate the CY 2026 PFS qualifying APM CF to be $33.5675 which reflects a 0.49 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.75 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2026 PFS nonqualifying APM CF to be $33.4009 which reflects a 0.49 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.25 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2026 anesthesia qualifying APM CF to be 20.5998 and the CY 2026 anesthesia nonqualifying APM CF to be 20.4976, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE DB-3: CALCULATION OF THE CY 2026 PFS QUALIFYING APM CONVERSION FACTOR

PFS Qualifying APM Conversion Factor	Percentage	Actual Adjustment	Conversion Factor
Conversion Factor in effect in CY 2025			32.3465
CY 2026 Qualifying APM Update Factor	0.75 percent	1.0075	
CY 2026 RVU Budget Neutrality Adjustment	0.49 percent	1.0049	
CY 2026 2.50 Percent Increase	2.50 percent	1.0250	

PFS Qualifying APM Conversion Factor	Percentage	Actual Adjustment	Conversion Factor
CY 2026 Conversion Factor			**33.5675**

TABLE D-B4: CALCULATION OF THE CY 2026 PFS NON-QUALIFYING APM CONVERSION FACTOR

PFS Non-Qualifying APM Conversion Factor	Percentage	Actual Adjustment	Conversion Factor
Conversion Factor in effect in CY 2025			32.3465
CY 2026 Non-Qualifying APM Update Factor	0.25 percent	1.0025	
CY 2026 RVU Budget Neutrality Adjustment	0.49 percent	1.0049	
CY 2026 2.50 Percent Increase	2.50 percent	1.0250	
CY 2026 Conversion Factor			**33.4009**

TABLE D-B5: CALCULATION OF THE CY 2026 ANESTHESIA QUALIFYING APM CONVERSION FACTOR

Anesthesia Qualifying APM Conversion Factor	Percentage	Actual Adjustment	Conversion Factor
Conversion Factor in effect in CY 2025			20.3178
CY 2026 Qualifying APM Update Factor	0.75 percent	1.0075	
CY 2026 RVU Budget Neutrality Adjustment	0.49 percent	1.0049	
CY 2026 2.50 Percent Increase	2.50 percent	1.0250	
CY 2026 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	-2.30 percent	0.9770	
CY 2026 Conversion Factor			**20.5998**

TABLE D-B6: CALCULATION OF THE CY 2026 ANESTHESIA NON-QUALIFYING APM CONVERSION FACTOR

Anesthesia Non-Qualifying APM Conversion Factor	Percentage	Actual Adjust.	Conversion Factor
Conversion Factor in effect in CY 2025			20.3178
CY 2026 Non-Qualifying APM Update Factor	0.25 percent	1.0025	
CY 2026 RVU Budget Neutrality Adjustment	0.49 percent	1.0049	
CY 2026 2.50 Percent Increase	2.50 percent	1.0250	
CY 2026 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	-2.30 percent	0.9770	
CY 2026 Conversion Factor			**20.4976**

Table D-B7 shows the impact on PFS payment for physicians' services based on the proposed policies included in this rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table D-B7 (CY 2026 PFS Estimated Impact on Total Allowed Charges by Specialty).

In recent years, we have received requests from interested parties to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented us with high-level information suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Some of the proposed policies in this rule are estimated to have significant differential effects depending on the site of service, especially the proposed changes to the allocation of indirect PE in the facility setting. Therefore, we published the impact tables including a facility/non-facility breakout of payment changes, as we believed that displaying the total impact by specialty alone, without the setting of care context, could be misleading for interested parties. The following is an explanation of the information represented in Table D-B7.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or non-facility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2024 utilization and CY 2025 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.

- Column D (Impact of Work RVU Changes): This column shows the estimated CY 2026 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column E (Impact of PE RVU Changes): This column shows the estimated CY 2026 impact on total allowed charges of the changes in the PE RVUs.
- Column F (Impact of MP RVU Changes): This column shows the estimated CY 2026 impact on total allowed charges of the changes in the MP RVUs.
- Column G (Combined Impact): This column shows the estimated CY 2026 combined impact on total allowed charges of all the changes in the previous columns. Column G may not equal the sum of columns D, E, and F due to rounding.

TABLE D-B7: CY 2026 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$213	0%	7%	0%	7%
	Non-Facility	$205	0%	8%	0%	8%
	Facility	$8	0%	-11%	0%	-11%
ANESTHESIOLOGY	*TOTAL*	$1,602	0%	-1%	0%	-1%
	Non-Facility	$311	0%	7%	0%	7%
	Facility	$1,290	0%	-3%	0%	-3%
AUDIOLOGIST	*TOTAL*	$75	0%	-1%	-1%	-1%
	Non-Facility	$72	0%	0%	-1%	0%
	Facility	$3	0%	-13%	-1%	-14%
CARDIAC SURGERY	*TOTAL*	$151	-1%	-3%	0%	-3%
	Non-Facility	$27	0%	7%	0%	6%
	Facility	$124	-1%	-5%	0%	-5%
CARDIOLOGY	*TOTAL*	$6,020	0%	1%	0%	1%
	Non-Facility	$3,759	0%	6%	0%	5%
	Facility	$2,261	-1%	-6%	0%	-7%
CHIROPRACTIC	*TOTAL*	$631	-1%	-1%	0%	-2%
	Non-Facility	$629	-1%	-1%	0%	-2%
	Facility	$2	-1%	-15%	0%	-17%
CLINICAL PSYCHOLOGIST	*TOTAL*	$733	3%	1%	-1%	3%
	Non-Facility	$594	3%	3%	-1%	5%
	Facility	$140	3%	-5%	-1%	-3%
CLINICAL SOCIAL WORKER	*TOTAL*	$1,019	4%	2%	-1%	4%
	Non-Facility	$879	4%	3%	-1%	6%
	Facility	$141	4%	-5%	-1%	-2%
COLON AND RECTAL SURGERY	*TOTAL*	$147	-1%	-2%	0%	-2%
	Non-Facility	$53	0%	7%	0%	7%
	Facility	$94	-1%	-7%	0%	-7%
CRITICAL CARE	*TOTAL*	$338	0%	-5%	0%	-4%
	Non-Facility	$55	0%	7%	0%	7%
	Facility	$283	0%	-7%	0%	-7%
DERMATOLOGY	*TOTAL*	$3,905	0%	-2%	0%	-2%
	Non-Facility	$3,763	0%	-1%	0%	-1%
	Facility	$142	-1%	-13%	0%	-14%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$920	0%	2%	0%	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
	Non-Facility	$919	0%	2%	0%	0%
	Facility	$2	-1%	0%	1%	-1%
EMERGENCY MEDICINE	*TOTAL*	$2,422	0%	-3%	1%	-1%
	Non-Facility	$221	0%	7%	0%	7%
	Facility	$2,201	0%	-4%	1%	-2%
ENDOCRINOLOGY	*TOTAL*	$528	0%	2%	0%	3%
	Non-Facility	$426	0%	6%	0%	6%
	Facility	$102	0%	-11%	0%	-10%
FAMILY PRACTICE	*TOTAL*	$5,461	0%	3%	0%	3%
	Non-Facility	$4,394	0%	6%	0%	6%
	Facility	$1,067	0%	-9%	0%	-9%
GASTROENTEROLOGY	*TOTAL*	$1,397	0%	-3%	0%	-4%
	Non-Facility	$505	0%	6%	0%	6%
	Facility	$891	-1%	-9%	0%	-10%
GENERAL PRACTICE	*TOTAL*	$378	0%	3%	0%	3%
	Non-Facility	$304	0%	5%	0%	6%
	Facility	$74	0%	-8%	0%	-7%
GENERAL SURGERY	*TOTAL*	$1,536	0%	-3%	0%	-3%
	Non-Facility	$449	0%	6%	0%	6%
	Facility	$1,086	-1%	-7%	0%	-7%
GERIATRICS	*TOTAL*	$201	1%	1%	0%	1%
	Non-Facility	$129	1%	8%	0%	8%
	Facility	$72	0%	-10%	0%	-9%
HAND SURGERY	*TOTAL*	$261	0%	0%	0%	-1%
	Non-Facility	$142	0%	5%	0%	5%
	Facility	$119	-1%	-7%	0%	-7%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,549	0%	0%	0%	0%
	Non-Facility	$995	0%	6%	0%	6%
	Facility	$555	0%	-11%	0%	-11%
INDEPENDENT LABORATORY	*TOTAL*	$551	0%	-1%	0%	-1%
	Non-Facility	$537	0%	-1%	0%	-1%
	Facility	$14	-1%	-1%	0%	-3%
INFECTIOUS DISEASE	*TOTAL*	$541	0%	-7%	0%	-6%
	Non-Facility	$86	0%	7%	0%	7%
	Facility	$455	0%	-10%	0%	-9%
INTERNAL MEDICINE	*TOTAL*	$9,446	0%	-2%	0%	-1%
	Non-Facility	$4,686	0%	6%	0%	6%
	Facility	$4,760	0%	-9%	0%	-8%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$829	0%	3%	0%	3%
	Non-Facility	$647	0%	7%	0%	6%
	Facility	$182	-1%	-8%	0%	-9%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$440	-1%	3%	0%	2%
	Non-Facility	$260	0%	9%	0%	7%
	Facility	$180	-2%	-5%	0%	-7%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$157	0%	-2%	0%	-2%
	Non-Facility	$78	0%	5%	0%	5%
	Facility	$78	0%	-9%	0%	-9%
NEPHROLOGY	*TOTAL*	$1,633	0%	0%	0%	1%
	Non-Facility	$976	1%	6%	0%	7%
	Facility	$657	0%	-9%	0%	-9%
NEUROLOGY	*TOTAL*	$1,319	0%	1%	0%	1%
	Non-Facility	$836	0%	6%	0%	6%
	Facility	$483	0%	-9%	0%	-9%
NEUROSURGERY	*TOTAL*	$687	-1%	-5%	0%	-5%
	Non-Facility	$116	0%	5%	0%	6%
	Facility	$571	-1%	-7%	0%	-7%
NUCLEAR MEDICINE	*TOTAL*	$48	-1%	0%	0%	-1%
	Non-Facility	$21	0%	1%	0%	1%
	Facility	$27	-1%	-1%	0%	-3%
NURSE ANES / ANES ASST	*TOTAL*	$1,064	0%	-2%	0%	-1%
	Non-Facility	$20	0%	9%	0%	10%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
	Facility	$1,044	0%	-2%	0%	-1%
NURSE PRACTITIONER	*TOTAL*	$7,750	0%	0%	0%	1%
	Non-Facility	$5,104	0%	5%	0%	5%
	Facility	$2,647	0%	-9%	0%	-9%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$543	0%	-1%	0%	-1%
	Non-Facility	$371	0%	4%	0%	4%
	Facility	$172	-1%	-10%	1%	-10%
OPHTHALMOLOGY	*TOTAL*	$4,457	0%	-1%	0%	-2%
	Non-Facility	$3,153	0%	3%	0%	3%
	Facility	$1,304	-1%	-12%	0%	-13%
OPTOMETRY	*TOTAL*	$1,365	0%	2%	0%	2%
	Non-Facility	$1,301	0%	3%	0%	3%
	Facility	$64	0%	-13%	0%	-13%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$45	0%	0%	0%	0%
	Non-Facility	$34	0%	4%	0%	4%
	Facility	$11	-1%	-10%	0%	-11%
ORTHOPEDIC SURGERY	*TOTAL*	$3,283	0%	-3%	0%	-3%
	Non-Facility	$1,450	0%	5%	0%	5%
	Facility	$1,833	-1%	-9%	0%	-9%
OTHER	*TOTAL*	$55	0%	-1%	0%	0%
	Non-Facility	$43	0%	1%	0%	3%
	Facility	$11	0%	-9%	0%	-9%
OTOLARNGOLOGY	*TOTAL*	$1,129	0%	1%	0%	0%
	Non-Facility	$895	0%	3%	0%	3%
	Facility	$233	-1%	-11%	0%	-12%
PATHOLOGY	*TOTAL*	$1,178	-1%	-2%	0%	-2%
	Non-Facility	$624	-1%	-1%	0%	-2%
	Facility	$554	-1%	-2%	0%	-3%
PEDIATRICS	*TOTAL*	$54	0%	1%	0%	2%
	Non-Facility	$35	0%	5%	0%	7%
	Facility	$19	0%	-8%	0%	-7%
PHYSICAL MEDICINE	*TOTAL*	$1,142	0%	-2%	0%	-2%
	Non-Facility	$543	0%	6%	0%	6%
	Facility	$600	0%	-9%	0%	-9%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$6,205	0%	-1%	0%	-1%
	Non-Facility	$6,205	0%	-1%	0%	-1%
	Facility	$	-1%	-6%	-1%	-7%
PHYSICIAN ASSISTANT	*TOTAL*	$3,938	0%	0%	0%	1%
	Non-Facility	$2,720	0%	4%	0%	4%
	Facility	$1,218	0%	-8%	0%	-8%
PLASTIC SURGERY	*TOTAL*	$290	-1%	-4%	0%	-4%
	Non-Facility	$128	0%	3%	0%	4%
	Facility	$161	-1%	-9%	0%	-10%
PODIATRY	*TOTAL*	$1,875	0%	1%	0%	2%
	Non-Facility	$1,663	0%	3%	0%	3%
	Facility	$211	0%	-8%	0%	-9%
PORTABLE **X**-RAY SUPPLIER	*TOTAL*	$80	0%	-1%	0%	-1%
	Non-Facility	$77	0%	-1%	0%	-1%
	Facility	$3	-1%	-1%	0%	-2%
PSYCHIATRY	*TOTAL*	$835	1%	0%	0%	0%
	Non-Facility	$505	1%	6%	0%	6%
	Facility	$330	1%	-9%	0%	-9%
PULMONARY DISEASE	*TOTAL*	$1,233	0%	-2%	0%	-1%
	Non-Facility	$538	0%	7%	0%	7%
	Facility	$695	0%	-8%	0%	-8%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,507	-1%	-1%	0%	-1%
	Non-Facility	$1,009	0%	-1%	0%	-1%
	Facility	$498	-1%	-1%	0%	-2%
RADIOLOGY	*TOTAL*	$4,515	-1%	-1%	0%	-2%
	Non-Facility	$1,972	0%	0%	0%	1%
	Facility	$2,543	-2%	-2%	0%	-3%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
RHEUMATOLOGY	*TOTAL*	$525	0%	4%	0%	4%
	Non-Facility	$470	0%	6%	0%	6%
	Facility	$55	0%	-12%	0%	-12%
THORACIC SURGERY	*TOTAL*	$290	-1%	-2%	0%	-3%
	Non-Facility	$55	0%	9%	0%	8%
	Facility	$235	-1%	-5%	0%	-5%
UROLOGY	*TOTAL*	$1,605	0%	0%	0%	0%
	Non-Facility	$1,127	0%	5%	0%	5%
	Facility	$479	-1%	-9%	0%	-10%
VASCULAR SURGERY	*TOTAL*	$934	0%	6%	0%	5%
	Non-Facility	$659	0%	11%	0%	9%
	Facility	$275	-1%	-7%	0%	-6%
TOTAL	***TOTAL***	$91,035	0%	0%	0%	**0%**
	Non-Facility	$57,776	0%	4%	0%	4%
	Facility	$33,259	0%	-7%	0%	-7%

* Column G may not equal the sum of columns D, E, and F due to rounding.

2. CY 2026 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for most specialties in the office-based setting, including surgical specialties, primary care specialties, behavioral health specialties, and those who furnish highly technical services outside of the hospital setting reflect significant increases relative to most of those same specialties in the facility setting. These increases can largely be attributed to, the proposed adjustment to indirect PE allocation in the facility setting. To a lesser degree, projected increases for some specialties, especially in primary care and behavioral health are driven by the redistributive effects of the proposed efficiency adjustment to work RVUs and the third year of the behavioral health work update. Increases are also due to proposed increases in valuation for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from supply and equipment pricing updates. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Lab Fee Schedule. Therefore, the estimated 1 percent increase for CY 2026 is only applicable to approximately 17 percent of the Medicare payment to these entities.

The estimated impacts for specialties in the hospital-based setting are driven primarily by the proposed adjustment to indirect PE allocation in the facility setting and the proposed efficiency adjustment. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized supply and equipment pricing updates. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased in over several years.

We note that several specialties appear on the specialty impacts table with both the largest projected increases in payment as well as the largest projected decreases in payment, split across the site of service differential.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table D-B7), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table D-B7 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As previously discussed, we have reviewed our suite of public use files and have worked on new ways to offer interested parties' additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2024 utilization data, Total RVUs change between -2 percent and 2 percent for roughly 25 percent of practitioners, representing approximately 32 percent of the changes in Total RVUs for all practitioners, with variation by specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule (see

https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates).

The specialty impacts displayed in Table D-B7 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from proposed policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) of the Act (such as the proposed the specialty impacts displayed in Table D-B7 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from proposed policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) of the Act (such as the proposed efficient adjustment or the proposed changes to indirect PE allocation in the facility setting) but does not include any changes in spending which result from proposed policies that are not subject to the statutory budget neutrality adjustment, and therefore, have a neutral impact across all specialties. The 0.75 percent and 0.25 percent updates to the CY 2026 qualifying APM and APM and nonqualifying APM conversion factors, respectively, as well as the single year increase of 2.50 percent to the conversion factor for CY 2026, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table D-B7.

b. Impact

Column G of Table D-B7 displays the estimated CY 2025 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high-volume procedures is available under "downloads" on the CY 2026 PFS proposed rule website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and non-facility rates are shown. For an explanation of facility and non-facility PE, we refer readers to Addendum A on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts Related to the Proposed Efficiency Adjustment

In section II.E.2.b of this final rule, we finalized the application of an efficiency adjustment to the work RVU and corresponding intraservice portion of physician time for non-time-based services as we

expect these kinds of services to accrue efficiencies over time. This applies to all codes except time-based codes, including but not limited to, E/M services, care management services, behavioral health services, services on the CMS telehealth list, and maternity codes with a global period of MMM, as well as new services. This efficiency adjustment policy will apply to all codes that are not otherwise excluded. Included code families represent the procedures, diagnostic tests, and radiology services that CMS expects to accrue efficiencies over time as changes in medical practice occur, including changes in clinician expertise, workflows, and technology.

The finalized efficiency adjustment for CY 2026 is calculated as the sum of the productivity adjustments used in the Medicare Economic Index (MEI) for the prior 5 years (2021 through 2025). The MEI is a measure of input price inflation faced by physicians and practitioners furnishing physicians' services such as physician's own time, non-physician employees' compensation, office rent, medical equipment, and more. The MEI productivity adjustment reflects the most recent historical estimate of the 10-year moving average growth of private nonfarm business total factor productivity, as calculated by the Bureau of Labor Statistics. Every year, the productivity adjustment is calculated by the CMS Office of the Actuary (OACT) based on the most recent historical data published by BLS at the time of the PFS final rule. Beginning in CY 2026, we are finalizing a 5-year look-back period to calculate the initial efficiency adjustment. See section II.E.2.b of this rule for more information on the proposed methodology. This calculation results in a proposed efficiency adjustment of 2.5 percent for CY 2026.

Generally, specialties that bill more often for timed codes, such as family practice, clinical psychologists, clinical social workers, geriatrics, and psychiatry would likely see an increase in RVUs; while specialties that bill more often for procedures, diagnostic imaging, and radiology services (such as radiation oncology, radiology, and some surgical specialties), would likely see a decrease in RVUs. This efficiency adjustment will decrease the work RVU for many services across most specialty types to reflect the efficiency gains that have taken place over time. Since this adjustment will reduce the work RVU for affected services, we project that there will be a net increase to the conversion factor as required under our budget neutrality provisions. We estimate that almost all specialties will experience no more than +1 or -1 percent change in RVUs as a result of this proposed policy, although the effect on individual services may be greater.

As stated in section II.E.2.b of this final rule, we finalized the proposed efficiency adjustment of 2.5 percent, and exempted additional codes, specifically time-based codes, services on the CMS telehealth list, and new codes for CY 2026, as reflected in the Codes Subject to Efficiency Adjustment public use file. This file can be found in the public use files for CY 2026; the file is available on the CMS website under downloads for the CY 2026 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

d. Estimated Impacts Related to the Proposed Site of Service Payment Differential

In section II.B. of this final rule, we proposed to, for each service valued in the facility setting, reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs for CY 2026.

Overall, specialties that practice primarily in the non-facility setting will see an increase in PE RVUs as a result of this redistribution. Specialties that perform services primarily in the facility setting will see a decrease in PE RVUs as a result of the proposed reduction to facility indirect PE. Overall, this proposed methodology change to indirect PE allocation will not affect the conversion factor, as all changes in valuation will be contained within the development of PE RVUs and redistribute PE RVUs from the facility to the non-facility setting.

E. Impact of Changes Related to Telehealth Services

We are finalizing as proposed the addition of several codes to the Medicare Telehealth Services List, including HCPCS codes G0473 and G0545, and CPT codes 90849, 92622, and 92623. We are not finalizing as proposed, the removal of HCPCS code G0136 from the Medicare Telehealth Services List. We are finalizing certain telecommunications technology-related flexibilities, including that we will continue to use a definition of direct supervision that allows "immediate availability" of the supervising practitioner using real-time audio and video interactive telecommunications for services without a 010 or 090 global period indicator. We are finalizing as proposed, eliminating the telehealth frequency limitations for subsequent nursing facility and inpatient hospital visits. While we noted that certain other Medicare telehealth flexibilities related to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID-19) (PHE for COVID-19) are expiring, including the removal of statutory geographic and location limitations for most Medicare telehealth services, the beneficiary's home

continues to be a permissible originating site for certain types of services including those furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including a Substance Use Disorder (SUD), and for monthly End Stage Renal Disease (ESRD) related clinical assessments described in section 1881(b)(3)(B) of the Act. However, expiration of certain flexibilities for Medicare telehealth services is not expected to impact broader utilization of these services because reasonable and necessary services for the diagnosis or treatment of an illness or injury continue to be covered. Despite the fact that some services will no longer be furnished under telehealth, we expect that they will continue to be furnished in-person. Therefore, we anticipate that our provisions will result in continued utilization of services that can be furnished as Medicare telehealth services during CY 2026 at levels comparable to observed utilization of these services during CY 2025.

F. Other Provisions of the Final Rule

1. Impact of Changes Related to Medicare Part B Payment for Skin Substitutes When Used During a Covered Application Procedure Under the PFS in the Non-facility Setting

As discussed in detail in section II.K.D. of this final rule, starting January 1, 2026, we are finalizing to pay for the provision of certain groups of skin substitute products used during a covered application procedure (CPT codes 15271 through 15278) as supplies. These skin substitutes will be paid as incident-to supplies under the PFS in the non-facility setting in accordance with section 1861(s)(2)(A) of the Act. While costs associated with supplies are usually bundled into the PE RVUs for particular services in non-facility settings, these products have been paid separately for many years in the non-facility setting, where the majority of these products are currently used.

As discussed in detail in section II.K. of this final rule, in light of our careful review of the applicable statutory provisions governing products paid under the ASP methodology under 1847A of the Act, the different FDA regulatory frameworks used for these products, and the skyrocketing increase in Medicare spending for such products, we proposed to pay separately for specific skin substitute products (other than products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act) that are eligible for Medicare coverage during a covered application procedure in the non-facility setting as incident-to supplies in accordance with section 1861(s)(2)(A) of the Act. To reflect relevant product characteristics, we are

finalizing to group skin substitutes that are not drugs or biologicals (that is, biological products licensed under section 351 of the PHS Act) using three CMS payment categories based on FDA regulatory pathways (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. We believe that finalizing to pay for these supplies as incident-to supplies under the PFS, valued in groups by how the products are used, better aligns payment with the resources involved in the provision of these incident-to supplies during a covered application procedure and will generate payment stability over time. In the proposed rule, we estimated that under the proposal, which assumed a single rate of approximately $125.38 for CY 2026, there would be an estimated savings of $9.4 billion, based on a single year comparison to 2024 using claims data available at that time.

Based on the Midsession Review of the 2026 President's Budget baseline, which was released in August of this year, we estimate that gross fee-for-service program spending for skin substitute services would be reduced by $19.6 billion in 2026. This impact is higher than prior estimates due to the incorporation of actual experience so far in 2025, which is significantly higher than estimated. This higher experience resulted in higher projected growth in spending for these services.

Because the resources involved in provision of these supplies were not previously incorporated into RVUs under the PFS, the costs are not accounted for when we compare the RVUs for physicians' services from 1 year to the next. In other words, changes in payment rates for these particular codes will be incorporated into PFS relativity once we use claims data from 2026, should the policy be finalized. Under the usual methodology, that means that changes in rates for these services between CY 2027 and CY 2028 would have an impact on the development of PE RVUs for other services. Over time, we anticipated that our proposal will continue to result in significant overall price reductions since grouped valuation instead of product-specific pricing should result in downward pricing pressure in the market. Additionally, we do not anticipate an impact to beneficiaries' access to appropriate care.

2. Drugs and Biological Products Paid Under Medicare Part B

a. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain

discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023, 2024, and 2025 PFS final rules, we finalized several policies to implement the provision. In December of 2024, CMS sent discarded drug refund reports for CY 2023 "new refund quarters," as defined at § 414.902. The total refunds owed for these quarters amount to over $139 million, which was deposited into the Supplementary Medical Insurance (SMI) trust fund, as required by law. In section III.A.1 of this final rule, we discuss two applications (CMS 10835, OMB 0938-1435) for increased applicable percentage which will have no impact on Medicare spending.

b. Average Sales Price**:** Price concessions and bona fide service fees (§§ 414.804 and 414.802)

In section III.A.2 of this final rule, we finalized modifications to two aspects of the calculation of manufacturer's Average Sales Price (ASP), including price concessions and bona fide service fees (BFSFs). Both price concessions and BFSFs have direct implications on the manufacturer's ASP. For example, if a manufacturer currently classifies an amount paid to an entity to be a BFSF but must reclassify the amount as a price concession under these proposed changes, the manufacturer's ASP would theoretically decrease. The resulting payment limit for the drug, typically ASP plus 6 percent, would also decrease. The opposite would also be true; that is, if a manufacturer considers an amount paid to an entity a price concession but then determines the amount to be a BFSF, the manufacturer's ASP would increase. However, we did not finalize the proposal to modify the definition of BFSF. Therefore, we anticipate that the finalized proposals will not have a significant impact on Medicare spending. Nevertheless, as the finalized policies will increase accuracy and transparency of ASP reporting, we anticipate that the finalized policy will likely result in reduced drug spending overall, resulting in decreases in ASP. If this occurs, there will be decreased spending on affected drugs. However, since details of arrangements and terms that manufacturers have with other entities are often not known to CMS, we are not able to quantify the possible changes in the payment limits for separately paid drugs under Medicare Part B.

c. Impacts Related to Autologous Cell-based Immunotherapy and Gene Therapy Payment

In section III.A.4. of this final rule, we finalized that preparatory procedures for patient-specific cell or tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself. Since the payment for preparatory procedures is an extension of the current policy for a subset of these products, Chimeric Antigen Receptor (CAR) T-cell therapies, and these products are furnished to very few beneficiaries, we do not anticipate the finalized policy to have a significant financial impact.

In addition, we are not finalizing the proposal that, beginning January 1, 2026 (that is, data reflecting sales beginning on that date), any preparatory procedures for patient-specific cell or tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that are paid by the manufacturer be included in the calculation of the manufacturer's ASP. Instead, when the four-part test at § 414.802 is satisfied, these manufacturer-paid amounts may be treated as BFSFs and excluded from ASP. Because we have little information about how manufacturers currently factor in the cost of cell or tissue procurement into pricing these products, we cannot predict the exact financial impact on Medicare payment. However, given that the cost of cell or tissue procurement is typically a very small fraction of the overall cost of the product and that some manufacturer-paid amounts may be excluded from ASP under this policy, we anticipate that any financial impact will not be substantial.

3. Impacts related to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this final rule, to continue alignment with the PFS and goals associated with APCM services, we finalized adoption of the add-on codes for APCM that would facilitate billing for BHI and CoCM services when RHCs and FQHCs are providing advanced primary care. We also finalized requiring RHCs and FQHCs to report individual codes that make up HCPCS code G0512. We also finalized requiring RHCs and FQHCs to report the individual codes that make up the communications technology-based services (CTBS), HCPCS code G0071. In addition, we finalized revisions to § 405.2464(c) and (e) to reflect our proposal on payment of CoCM and CTBS services for RHCs and FQHCs. We also finalized the proposal to adopt services that are established and paid under the PFS and designated as care management services as care coordination services for purposes of separate payment for RHCs and FQHCs. In terms of the estimated impacts to the Medicare program, we

believe that the finalized policies discussed in section III.B.2 of this final rule will have a negligible impact on Medicare spending.

In section III.B.3 of this final rule, we finalized the policy to adopt the definition "immediate availability" as including real-time audio and visual interactive telecommunications for the direct supervision permanently for all RHC and FQHC services and the definition of physician supervision at § 405.2401(b). We finalized, on a temporary basis, to facilitate payment for non-behavioral health visits furnished via telecommunication technology using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2026. We also finalized that, beginning October 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record. As such, finalized revisions to 42 CFR part 405, subpart X, specifically, at § 405.2463(b)(3), ''What constitutes a visit,'' and, at § 405.2469(d) ''FQHC supplemental payments,'' as proposed.

We believe these RHC/FQHC policies related to telecommunication technology will have a negligible impact on Medicare spending.

4. Ambulatory Specialty Model (ASM)

a. Scale of the Model

As we discuss in sections III.C.2.c.(4) and III.C. l. of this final rule, there is no one-size-fits-all approach to designing, implementing, and evaluating Innovation Center models. Each payment and service delivery model tested by the Innovation Center is unique in its goals, and thus its design. Models vary in size to accommodate various design features and satisfy a variety of priorities. Decisions made

regarding the features and design of the model strongly influence the extent to which the evaluation will be able to accurately assess the effect of a given model test and produce clear and replicable results.

The Innovation Center conducts analyses to determine the ideal number of participants for each model for evaluation purposes. This analysis considers a variety of factors including the target population (for example, Medicare beneficiaries with select chronic conditions), model eligibility (for example, participant eligibility criteria for inclusion in the model), participant enrollment strategy (for example, mandatory versus voluntary) and, the need to test effects on subgroups. Model size can also be influenced by the type and size of hypothesized effect on beneficiary outcomes, such as quality of care, or the target level of model savings. The smaller the expected impact a model is hypothesized to achieve, the larger a model needs to be for CMS to have confidence in the observed impacts.

An insufficient number of participants increases the risk that the evaluation will be imprecise in detecting the true effect of a model, potentially leading, for example, to a false negative or false positive result. The goal is to design a model that is sufficiently large to achieve adequate precision but not so large as to waste CMS' limited resources. These decisions affect the quality of evidence CMS can present regarding the impacts of a model on quality of care, utilization, and spending.

In the case of ASM, in this final rule we have determined the sample size necessary for a minimum estimated savings impact of 3.5 percent. While savings higher than 3.5 percent would require a smaller sample size from an evaluation perspective, if we were to reduce the size of ASM and if the actual savings are at or just below the 3.5 percent level, then we would increase the risk of being unable to detect whether ASM resulted in savings.

We expect that ASM will include approximately 25 percent of all CBSAs and metropolitan divisions. As finalized at § 512.710(f), a CBSA or metropolitan division must have at least one clinician of the required specialty types who furnished at least 20 eligible episodes heart failure and at least one clinician of the required specialty types who furnished at least 20 eligible low back pain episodes between January 1, 2024 and December 31, 2024 to be eligible for selection into ASM. We performed a simulation based on our proposed policies. We simulated the random selection of CBSAs and metropolitan divisions using CY 2023 data based on the methodology finalized at § 512.710(f), which will allow us to detect the minimum estimated savings impact of 3.5 percent described earlier in this section of this final rule.

Based on this simulation, we expect to have approximately 3,400 ASM heart failure participants billing under 1,160 TINs and approximately 5,200 ASM low back pain participants billing under 2,400 TINs in the simulated mandated geography areas. Within the ASM heart failure cohort, we expect ASM to include approximately 164,000 unique heart failure episodes, 162,600 unique beneficiaries triggering episodes, and $1.6 billion in total episode FFS spending (Medicare Part A and Part B only) of allowed charges for each ASM performance year. Within the ASM low back pain cohort, we expect ASM to include approximately 441,000 unique low back pain episodes, 398,500 unique beneficiaries triggering episodes, and $1.2 billion in total episode FFS spending of allowed charges for each ASM performance year. To determine the number of ASM participants in each ASM cohort, we counted the number of clinicians in mandatory geographic areas (as described at § 512.710(f)) with the selected specialty types (as described at § 512.710(d)) that furnished at least 20 episodes related to the ASM's cohort targeted chronic condition in CY 2023 (as described at § 512.710(e)). Similarly, to determine episode count, beneficiary count, and total spending estimates, we drew upon the historical data of ASM participants in the simulated mandatory geographic areas selected for participation.

We solicited public comments on the proposed scale of ASM.

We did not receive public comments on the scale of ASM, and therefore, we are finalizing provisions related to the random selection of CBSAs as described at § 512.720(f). We refer readers to section III.C.2.c.(4). of this final rule for a summary of comments received related to ASM's mandatory geographic areas and our responses.

b. Effects on ASM Participants

ASM will not alter the way ASM participants bill Medicare. Therefore, we believe that there will be no additional burden for ASM participants related to billing practices.

We believe the audit and retention policies of ASM are generally consistent with existing policies under Medicare. Additionally, the monitoring requirements for ASM are consistent with the monitoring and evaluation requirements already in place under 42 CFR 405.1110(b) for participants in models tested under section 1115A of the Act. Therefore, we believe the audit and retention policies and the monitoring and evaluation requirements do not add additional regulatory burden on ASM participants.

We do not believe that the model evaluation for ASM would include beneficiaries or clinicians completing surveys.

We estimated the administrative costs of adjusting to and complying with the measure reporting requirements for ASM to be approximately $3,077.36 per ASM participant per year. We believe the burden estimate for submitting data to meet the proposed quality, improvement activities, and Promoting Interoperability measure reporting requirements in sections III.D.C.d.(2)., III.C.2.d.(4)., and III.C.2.d.(5). of this final rule will apply to ASM participants that are and are not considered small entities (see section VI.E.7.b.(1). of this final rule for further discussion on the estimated effects of ASM on small businesses). To estimate the costs per ASM participant, we estimate the burden for submitting data in the quality, improvement activities, and Promoting Interoperability ASM performance categories generally using the same assumptions for time and labor categories for the staffing that the Quality Payment Program uses for MVP submissions in section V. of this final rule. As discussed in section III.C.2.d.(1).(b). of this final rule, ASM participants will not need to submit data for the cost ASM performance category and the administrative claims measures in the quality ASM performance category. Therefore, we did not estimate burden for the administrative claims measures in the cost and quality ASM performance categories.

To estimate the burden for submitting quality measure data for an ASM cohort as described in section III.C.2.d.(2). of this final rule, we assume 50 percent of the ASM participants will submit data on quality measures using the eCQM collection type, and the remining 50 percent of the ASM participants would submit data using the MIPS CQM collection type. For an ASM participant to submit a quality measure using the eCQM collection type, we assume it will take a total of 5.3 hours [1.33 hours for a computer system analyst to submit data, 1.33 hours for a Medical and Health Services Manager to review the measure specifications, and 0.66 hours each for a computer system analyst, Licensed Practical Nurse (LPN), billing clerk, and physician to review the measure specifications]. For an ASM participant to submit a quality measure using the MIPS CQM collection type, we assume it will take a total of 5.97 hours [2 hours for a computer system analyst to submit data, 1.33 hours for a Medical and Health Services Manager to review the measure specifications, and 0.66 hours each for a computer system analyst, LPN, billing clerk, and physician to review the measure specifications]. To calculate the estimated cost, we used the May 2024 wage rate data from the U.S. Department of Labor

(https://www.bls.gov/oes/current/oes_nat.htm) and doubled the mean hourly wage to account for overhead and benefits. Accounting for overhead and benefits, we used salary estimates of $107.66/hr for a computer systems analyst, $132.44/hr for a Medical and Health Services Manager, $61.68/hr for a LPN, $47.60/hr for a billing clerk, and $296.74/hr for a physician. We estimated it would require ASM participants approximately 21.2 hours (4 eCQM measures x 5.3 hours) to submit data using the eCQM collection type or 23.88 hours (4 MIPS CQMs x 5.97 hours) to submit data using the MIPS CQM collection type for the required four quality data measures once annually. We estimate it would cost $658.37 (1.33 hours x $107.66/hr + 1.33 hours x $132.44/hr + 0.66 hours x $61.68/hr + 0.66 hours x $47.60/hr + 0.66 hours x $296.74/hr) per measure to submit quality data using the eCQM collection type and $730.50 (2 hours x $107.66/hr + 1.33 hours x $132.44/hr + 0.66 hours x $61.68/hr + 0.66 hours x $47.60/hr + 0.66 hours x $296.74/hr) per measure to submit quality data using the MIPS CQM collection type. Therefore, we estimate the total annual cost for an ASM participant to submit the required measures in the quality ASM performance category using the eCQM collection type would be $2,633.48 (4 eCQM measures x $658.37) or $2,922 (4 MIPS CQM measures x $730.50) using the MIPS CQM collection type.

We also estimate that data submission of the proposed improvement activities discussed in section III.C.2.d.(4). of this final rule will take 0.083 hours (or 5 minutes) and will be required once annually per ASM participant. Data submission for the Promoting Interoperability measures discussed in section III.C.2.d.(5). of this final rule will take 2.7 hours and will occur once annually per ASM participant. We used the salary estimate of $107.66/hr for a computer systems analyst to estimate burden for submitting data in the Promoting Interoperability and improvement activities ASM performance categories. For an ASM participant to submit data for the improvement activities ASM performance category, we estimate it will cost $8.94 ($107.66/hr x 0.083 hours x 1 submission). For data submission for the Promoting Interoperability ASM performance category, we estimate it will cost $290.68 ($107.66/hr x 2.7 hours x 1 submission). We estimate that the burden for collecting and reporting quality, improvement activities, and Promoting Interoperability measures for an ASM participant submitting data using the eCQM collection type will be 23.983 hours (21.2 hours + 0.083 hours + 2.7 hours) at a cost of $2,933.10 ($2,633.48 + $8.94 + $290.68) and 26.663 hours (23.88 hours + 0.083 hours + 2.7 hours) at a

cost of $3,221.62 ($2,922 + $8.94 + $290.68) for an ASM participate submitting data using the MIPS CQM collection type. We estimate approximately 7,622 ASM participants that will report data, therefore, the total burden estimate for all ASM participants collecting and reporting the measures in the quality, improvement activities, and Promoting Interoperability performance categories will be approximately 193,012 hours (23.983 hours x 3,811 ASM participants + 26.663 hours x 3,811 ASM participants) at a cost of $23,455,621 ($2,933.10 x 3,811 ASM participants + $3,221.62 x 3,811 ASM participants).

Additionally, we assume that approximately 50 percent of ASM participants that are currently not participating in MIPS will need to submit a one-time registration to access the CMS Enterprise Portal User Account (EUA). We estimate that it will take approximately 1 hour for an ASM participant or their representative to submit the registration for EUA. We used the salary estimate of $107.66/hr for a computer systems analyst to submit the registration for EUA access. Therefore, we estimate it will cost $107.66 ($107.66/hr x 1 hour) per registration. We estimate approximately 530 ASM participants will submit the application for EUA access. Therefore, the total burden estimates for ASM participants submitting the registration for EUA access will be approximately 530 hours at a cost of $ 57,059.80 (530 hours x $107.66/hr). We note that we did not include the estimated burden for submitting the registration for EUA access in calculating the total estimated burden per ASM participant as this submission does not occur annually.

We solicited public comments on our proposed estimated burden impacts on ASM participants.

We did not receive public comments about the estimated burden impacts on ASM. Therefore, we refer readers to section III.C.2 of this final rule for summaries of comments received, our responses to those comments, and our finalized provisions related to ASM.

c. Effects on Small Entities

As described in section VI.H of this final rule, the RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. HHS uses an RFA threshold of at least a 5 percent impact on the affected entities within an identified industry to determine whether a proposed rule is likely to have “significant” impacts on small

entities.[479] Approximately 95 percent of practitioners, other suppliers, and providers are considered small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. Although many ASM participants may be small entities as that term is used in the RFA, the proportion of revenue from Medicare Part B covered professional services to which ASM would adjust payments would represent a small fraction of revenue generated by the ASM participant.

Our analysis assumed that ASM would include only Medicare FFS beneficiaries receiving services from ASM participants. During 2024, 53.3 percent of Medicare beneficiaries with both Medicare Part A and Part B coverage on average are estimated to be enrolled in Medicare Advantage plans.[480] ASM participants may also serve patients with other coverage, such as Medicaid or commercial insurance. Given that ASM would only adjust payments to Medicare Part B payments for covered professional services based on performance—not other revenue from other payers like Medicare Advantage and commercial insurance that we expect to be about 50 to 60 percent of total revenue combined—we expect that the anticipated average impact of revenue based solely on Medicare Part B payments for covered professional services to be less than 1 percent. Therefore, we determine that the finalized provisions of ASM will not have a greater than 5 percent impact on total revenues on a substantial number of small entities.

As discussed in section VI.E.b.(1). of this final rule, we believe that burden estimate of reporting the required measures and activities for ASM will be the same for ASM participants regardless of their small business status.

We solicited public comments on our analysis that estimates no differential impact of ASM on small entities.

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[479] Office of Advocacy, Small Business Administration. (2012). A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272, Retrieved from www.sba.gov/sites/default/files/rfaguide_0512_0.pdf (accessed March 18, 2019).

[480] This figure comes from the 2024 Medicare Trustees Report, Table IV.C1, p157 from the footnote that has the A and B share.

We did not receive public comments on the impact of ASM on small entities. Therefore, we refer readers to section III.C.2 of this final rule for summaries of comments received, our responses to those comments, and our finalized provisions related to ASM.

d. Effects on the Medicare Program

(1) Overview

Under the current Medicare FFS payment system, services are paid on a per service basis to clinicians through the PFS. As a mandatory model, ASM will test whether rewarding clinicians based on measures of quality, cost, care coordination, and CEHRT interoperability results in enhanced quality of care and reduced costs through more effective upstream chronic condition management. ASM will test adjusting Medicare Part B covered professional services claims of an ASM participant according to a payment adjustment that is determined by an ASM participant's performance on a set of measures they must report (see sections III.C.2.d and III.C.2.f of this final rule). For each ASM participant, the payment adjustment amount will be determined as proposed at § 512.750.

ASM is not a total cost of care model. ASM participants will still bill traditional FFS Medicare for services as usual.

(2) Data and Methods

A simulation based on the proposed policies was created to estimate the financial impacts of ASM. The simulation relied upon simulated final scores and ASM payment adjustments, as well as assumptions derived from EBCM episodes related to ASM's targeted chronic conditions from CY 2023 and Medicare FFS claims data. We reviewed these assumptions and determined them to be reasonable for the estimates.

We simulated an ASM final score based on the methodology described in sections III.C.2.d and III.C.2.e of this final rule.

For scoring the quality ASM performance category, we first made assumptions on who would report based on whether clinicians were engaged in the CY 2023 MIPS performance period/2025 MIPS payment year and submitted data. We believe that historical engagement and submission of data to MIPS would be an appropriate predictor of an ASM's participant likelihood to submit data to meet ASM's requirements. For clinicians we identified as engaged, we assumed the ASM participants would report all

required quality measures (meeting data completeness requirements and case minimum requirements) as discussed in section III.D.2.d.(2). For ASM participants who were eligible for the 2023 MIPS performance period/2025 MIPS payment year, we generally assigned participants as engaged or not engaged based on their 2023 MIPS participation. We carved out an exception for clinicians who were labeled "not engaged" in MIPS but had MIPS final scores of 75 as we believe most of these clinicians received extreme and uncontrollable circumstances approval (which will result in a final score of 75 points equal to the MIPS performance threshold).[481] For these participants, we cleared the engaged status flag. For ASM participants who did not have a populated engaged status flag (either because they were not eligible for CY 2023 MIPS performance period/2025 MIPS payment year or because we cleared their engaged status flag as described earlier), we randomly assigned engaged and not engaged flags, based on practice size, to mimic the proportion of ASM participants who were engaged and not engaged in the CY 2023 MIPS performance period/2025 MIPS payment year. This process resulted in all ASM participants receiving an engaged or not engaged assumption for the purpose of simulating a final score and payment adjustment.

In calculating a quality ASM performance category score for engaged participants (and we assumed participants would submit all quality measures meeting data completeness and case minimum requirements), we did not have adequate historical MIPS performance data for the proposed measures in sections III.C.2.d.(2).(b) and III.C.2.d.(2).(c). of this final rule. Therefore, we randomly assigned measure achievement points for each proposed ASM measure. The values ranged from 1 to 10 based on decile benchmarks to simulate performance using benchmarks based on ASM participants only. We recognize that this method may not accurately assign performance for an individual. However, we believe it approximates the relative differences within a benchmark distribution and represents the best available approach given that most ASM participants that previously participated in MIPS did not submit the proposed quality ASM performance category measures in MIPS.

For the ASM participants we identified as not engaged and assumed they would not submit quality measures, we assigned a score of zero for the quality ASM performance category. Ultimately, these non-engaged ASM participants received an ASM final score of zero in our model for not meeting

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[481] We also excluded one participant, who was facility-based, who had a score greater than 75.

the required minimum data submission requirements, as discussed in section III.C.2.e.(2) of this final rule.

For the cost ASM performance category score proposed in section III.C.2.d.(3) of this final rule, we assigned measure achievement points and calculated a cost ASM performance category score using heart failure and low-back pain episode-based cost measure files based on CY 2023 administrative claims data.

To simulate the improvement activity ASM performance category score and scoring adjustment that is proposed in section III.C.2.d.(4).(d). of this final rule, we relied on the same engagement assumptions that we used for the quality ASM performance category. We assumed that engaged ASM participants will also report all the required improvement activities. These ASM participants would have an improvement activities ASM performance category score of 100 percent and will not have any negative ASM improvement activities scoring adjustment. For ASM participants we identified as not engaged, we assigned an ASM performance category score of zero and an improvement activities ASM performance category scoring adjustment of negative 20 points.

For the Promoting Interoperability ASM performance category, we calculated the Promoting Interoperability ASM performance category score and scoring adjustment discussed in section III.C.2.d.(5).(e). of this final rule using proxies for the Promoting Interoperability ASM performance category score. Our primary proxy for the Promoting Interoperability ASM performance category score was to use the CY 2023 MIPS performance period/2025 MIPS payment year Promoting Interoperability performance category score where it was available. The Promoting Interoperability ASM performance category scoring adjustment was calculated using the formula discussed in section III.C.2.e.(1). of this final rule. If an ASM participant was not eligible for the 2023 MIPS performance period/2025 MIPS payment year, we assumed that the Promoting Interoperability ASM performance category score will be 100, as over half of potential ASM participants that were eligible in the CY 2023 MIPS performance period/2025 MPS payment year and reported Promoting Interoperability information had a Promoting Interoperability performance category score of 100. ASM participants with a Promoting Interoperability ASM performance category score of 100 would not have a negative scoring adjustment for the Promoting Interoperability ASM performance category. For ASM participants who were in the CY 2023 MIPS

performance period/2025 MIPS payment year but did not have a 2023 MIPS Promoting Interoperability performance category score because the performance category was reweighted, we assumed these participants may not have CEHRT and thus may not be able to report measures for the Promoting Interoperability ASM performance category. For these ASM participants, we assumed a Promoting Interoperability ASM performance category score of 0 which translates into a Promoting Interoperability ASM performance category scoring adjustment of negative 10 points. We anticipated that these clinicians could use CEHRT in the future and that we may be overestimating the number of ASM participants without CEHRT.

Finally, we simulated a final score for each ASM participant using the formula proposed in section III.C.2.e. of this final rule. As described in this same section, we utilized scores for the quality and cost ASM performance categories and the scoring adjustments for the improvement activities and Promoting Interoperability ASM performance categories. We also calculated a complex patient scoring adjustment, described in section III.C.2.e.(3). of this final rule, and applied a small practice scoring adjustment, described in section III.C.2.e.(4). of this final rule, using variables in the Quality Payment Program final eligibility file for the CY 2023 MIPS performance period/2025 MIPS payment year. As described earlier in this section, any ASM participants who we assumed would not be engaged, were assigned a final score of zero points.

Using the simulated final scores for ASM participants, we simulated the resulting payment adjustments using the methods described in section III.C.2.f. of this final rule. We used Medicare Part B paid amounts from claims for covered professional services in CY 2023 to calculate each ASM incentive pool. For each ASM cohort, we calculated the scaling factor and the resulting ASM payment adjustment factor and ASM payment multiplier for each ASM participant based on their final score and the proposed logistic exchange function with a midpoint at the median final score for the applicable ASM cohort.

We solicited comments on our methods to estimate an ASM final score, ASM payment adjustment factor, and ASM payment multiplier for each ASM participant.

We did not receive public comments on the data and methods used to simulate an ASM final score, ASM payment adjustment factor, and ASM payment multiplier for each ASM participant.

Therefore, we refer readers to section III.C.2 of this final rule for summaries of comments received, our responses to those comments, and our finalized provisions related to ASM.

(3) Medicare Estimates

In this final rule, we summarized the estimated impact of ASM in Table D-B8. We estimate a net impact of $177 million in net savings to the Medicare program due to ASM from January 1, 2029 through December 31, 2033.

The estimated impact reflects the finalized provisions described in this final rule. To summarize relevant finalized provisions, we will test ASM for five performance years from January 1, 2027 through December 31, 2031 with payment adjustments occurring in corresponding ASM payment years from January 1, 2029 through December 31, 2033. As discussed earlier in this section of this final rule, ASM will operate in 25 percent of all CBSAs and metropolitan divisions. ASM participants will be subject to a maximum risk level for each ASM payment year, which will would range from 9 percent to 12 percent over the ASM test period, and under which an ASM participant will receive an ASM payment adjustment factor based on their final score and the amount of each ASM incentive pool distributed to each ASM cohort in the form of scaled payment adjustments.

The estimated impact uses Medicare Part B paid amounts for covered professional services attributed to the simulated ASM participants in CY 2023 to determine the baseline spending. We trended the baseline spending in CY 2023 forward to the ASM payment years (CY 2029 through CY 2033) using the trend assumptions underlying the 2024 Medicare Trustees Report. We calculated the financial impact percentage as the downward ASM risk level (that is, the percentage of ASM participant spending at risk for each ASM participant for a given ASM payment year) multiplied by 15 percent (that is, the average amount of the ASM incentive pool that will not be distributed to ASM participants in the form of payment adjustments). We applied this financial impact percentage to the trended baseline spending for each ASM payment year. The estimates in Table D-B8 do not account for behavioral effects that could occur as a result of implementing ASM. We refer readers to the sensitivity analysis later in this section of this final rule for further discussion on potential behavioral effects on spending as a result of ASM.

Thus, we estimate that the Medicare program would save $177 million over ASM's model test period. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

TABLE D-B8: ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR THE AMBULATORY SPECIALTY MODEL (Starting January 1, 2029)

Year	2029	2030	2031	2032	2033	Total
Baseline Spending ($M)	$2,171.3	$2,235.9	$2,302.4	$2,368.5	$2,439.1	$11,517.2
Financial Impact (%)	-1.35%	-1.35%	-1.50%	-1.65%	-1.80%	-1.54%
Financial Impact ($M)	-$29.3	-$30.2	-$34.5	-$39.1	-$43.9	-$177.0

We solicited public comments on our estimated impact of ASM on the Medicare program.

We did not receive public comments about our estimated impact of ASM on the Medicare program. Therefore, we refer readers to section III.C.2 of this final rule for summaries of comments received, our responses to those comments, and our finalized provisions related to ASM.

(i) Sensitivity Analysis

ASM participants will receive payment adjustments based on their final scores. We expect these payment adjustments to incentivize participants to improve their ASM performance category scores, which will impact costs. The degree to which the participants will be incentivized to alter their behavior will depend on the magnitude of the payment adjustments, and the magnitude of the payment adjustment, including whether it is positive or negative, depends on the distribution of final scores used in the payment adjustment calculation. Since that distribution is unknown, we have not incorporated behavioral effects into the estimate.

There is evidence that shows that delivering higher-value care could lead to savings for Medicare. For example, better adherence to clinical guidelines for heart failure patients under ASM could reduce the number of hospitalizations that occur among ASM beneficiaries. Since hospitalizations and associated costs comprise a large share of total heart failure patient spending, such changes could reduce spending significantly. Similarly, improved adherence to clinical guidelines for low back pain could lead to lower rates of imaging service use, fewer invasive surgeries, and lower spending among ASM beneficiaries. However, it is unknown how well these changes in care patterns could ultimately be implemented.

Alternatively, some of the quality measures used in determining final scores could motivate ASM participants to deliver more services than they would have absent the model. For example, preventive care and screening metrics for BMI and depression could incentivize participants to provide more care for some patients with low back pain, and metrics on controlling high blood pressure could have a similar effect. Another consideration is that ASM participants could react to negative payment adjustments with adverse behavior (for example, increasing coding intensity) to help offset revenue losses.

To explore the potential financial impacts of these behavioral effects, we adjusted the original impact estimates under several illustrative scenarios using different amounts of behavioral effects, measured in percent change in spending. Table D-B9 shows estimated financial impacts on total Medicare Parts A and B spending from heart failure and low back pain episodes attributed to our simulated ASM participants based on the estimated behavioral effect levels. The estimated financial impacts presented in Table D-B9 present one set of assumptions on the behavioral effect on spending; the behavioral impact on spending could be larger in magnitude than the illustrative scenarios here. The resulting financial impact estimates (in millions of dollars) of each scenario in Table D-B9 represent the total estimated impact across ASM's test period.

TABLE D-B9: ASM FINANCIAL IMPACT BY ILLUSTRATIVE BEHAVIORAL EFFECTS ON SPENDING, CY 2029 THROUGH CY 2033

Behavioral Effect	Adjusted Financial Impact ($M)
-2%	-$526.7
-1%	-$351.9
0%	**−$177.0***
1%	-$2.2
2%	$172.7

* The adjusted financial impact without any behavioral effects is equal to the total estimated financial impact during ASM's test period included in **Table D-BXX**.

We solicited public comments on our sensitivity analysis related to the estimated financial impacts of ASM.

We did not receive public comments on our sensitivity analysis related to the estimated financial impacts of ASM on the Medicare program. Therefore, we refer readers to section III.C.2. of this final rule for summaries of comments received, our responses to those comments, and our finalized provisions related to ASM.

e. Effects on the Market

There could be spillover effects in the non-Medicare market, because of the implementation of ASM. Testing changes in Medicare payment policy may have implications for non-Medicare payers. For example, non-Medicare patients may benefit if participating providers and suppliers introduce system-wide changes that improve the coordination and quality of health care. Other payers may also be developing payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS' evaluations of payment models. Because there is uncertainty about whether and how this evidence applies to a test of these new payment models, our analyses assume that spillover effects on non-Medicare payers would not occur, although this assumption is subject to considerable uncertainty. We solicit comments on this assumption and evidence on how this rulemaking would impact non-Medicare payers and patients.

We solicited public comments on our impact of ASM on the market.

We did not receive public comments on our estimated impact of ASM on the market. Therefore, we refer readers to section III.C.2. of this final rule for summaries of comments received, our responses to those comments, and our finalized provisions related to ASM.

5. Impact of Provisions for Medicare Prescription Drug Inflation Rebate Program

In this final rule, we finalized new policies to implement the Medicare Part B Drug Inflation Rebate Program, including CMS' method for calculating the payment amount in the payment amount benchmark quarter if a published payment limit is not available or if there is no published payment limit and neither positive Average Sale Price (ASP) nor positive Wholesale Acquisition Cost (WAC) data are available in the ASP Data Collection System. Additionally, we finalized revised and new policies to implement the Medicare Part D Drug Inflation Rebate Program, including but not limited to, a claims-based methodology to implement § 428.203(b)(2), which provides that, for claims with dates of service on or after January 1, 2026, and with respect to an applicable period, CMS will exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program and the establishment of a Part D claims data 340B repository to receive voluntary submissions from 340B covered entities of certain data elements from Part D 340B claims.

We do not expect the proposed policies regarding the Medicare Part B and Part D Drug Inflation Rebate Program to have a material impact on the calculation of total rebates in aggregate, as these proposals are refinements to regulatory requirements and do not otherwise change the scope of rebatable drugs.

In the CY 2025 PFS final rule (89 FR 98593), CMS finalized the proposal at § 428.203(b)(2)(i) to exclude from the total number of units determined at § 428.203(a) units for which a manufacturer provided a discount under the 340B Program ("340B units"), as well as the proposal at § 428.203(b)(2)(ii) to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. However, after consideration of the data limitations of the proposed estimation methodology and public comments, CMS did not finalize the proposed estimation methodology for the applicable period that begins on October 1, 2025. Instead, CMS stated that it would explore avenues to implement section 1860D-14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a 340B repository. CMS did not repropose the estimation methodology proposed in the CY 2025 PFS proposed rule but did consider this estimation percentage as an alternative to the proposal this year, as described in section III.E.3.c.iii. of this final rule titled "Alternative Policy Considered". Rather, we finalized at § 428.203(b)(2) implementation of a claims-based methodology to remove 340B units beginning January 1, 2026. We also finalized the establishment of a 340B repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying 340B units for removal in a future applicable period.

We do not anticipate our inflation rebate proposed policies will result in an incrementally significant financial impact on the Medicare program relative to a baseline that reflects the status quo in the absence of any modifications to inflation rebate regulations at parts 427 and 428 as these finalized policies are refinements to regulatory requirements.

We did not receive public comments on these provisions, and therefore, we are finalizing as proposed.

6. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2025, 11.2 million Medicare beneficiaries receive care from a healthcare provider in one of the 477 ACOs participating in the Shared Savings Program.[482] The modifications to the Shared Savings Program policies we are finalizing in this final rule are designed, in part, to further improve the quality of care furnished by ACOs by revising the quality performance standard and reporting requirements, encourage more ACOs to move to a two-sided risk model, and promote the continued integrity and fairness of Shared Savings Program financial calculations.

As we described in the CY 2026 PFS proposed rule (90 FR 32814), the ACOs in the program in performance year 2023 combined to cover $128 billion in benchmark target spending. Actual ACO spending totaled approximately $123 billion – about $5.2 billion below combined benchmark. After accounting for $3.1 billion in net shared savings to ACOs, the remaining difference of $2.1 billion would represent federal savings from the program if benchmarks proved to be a perfect counterfactual in aggregate. The Regulatory Impact Analysis in the December 2018 final rule (see 83 FR 68044 through 68050) provided evidence that the benchmarks for performance year 2016 combined to represent a lower spending target than the theoretical counterfactual for estimating what spending would have been in the total FFS Medicare Program had ACOs not been present that year. Evidence included all of the following:

● Lower combined market level spending trends observed for cohorts of Hospital Referral Regions (HRRs) with significant ACO formation relative to other HRRs without material ACO activity.

● Spillover effects on spending outside of ACO benchmarks, including non-assigned beneficiaries served by ACO providers and suppliers.

● Program design elements that restrained benchmark levels, including rebasing with agreement periods of only 3 years, feedback of communal ACO effects on national trends used to update benchmarks, and restrictions on risk adjustment.

The Regulatory Impact Analysis in the December 2018 final rule (83 FR 68048) estimated that ACOs may have been responsible for half of the 1.2 percent difference in spending trend observed

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[482] See "Shared Savings Program Fast Facts – As of January 1, 2025", available at https://www.cms.gov/files/document/2025-shared-savings-program-fast-facts.pdf.

between national average and the subset of HRRs with minimal ACO activity through 2016. This scaled impact represented about four times the gross savings measured relative to benchmarks, or about 0.5 percent net savings across the entire FFS program after accounting for shared savings payments despite benchmarks only officially showing roughly equivalent overall reductions in spending relative to benchmark compared to total outlays from shared savings payments. Since 2016, changes to the Shared Savings Program have potentially moved the benchmarks closer to what the spending would have been in the absence of the program.

In the CY 2026 PFS proposed rule (90 FR 32814 through 32815), we explained that updating the earlier study to compare more recent trends for markets with varying levels of ACO activity requires updates to the initial study approach, as ACOs have become active in an increasing majority of markets across the nation. There no longer exists a sufficient number of HRRs with nominal ACO penetration in 2023 to construct a de facto counterfactual similar to the study in the December 2018 final rule. An alternate method, however, continues to show spending trends inversely correlated with ACO penetration over time. Roughly 5 percent of beneficiaries live in HRRs with ACO penetration consistently below the national average by 10 percentage points or more over the 2013 to 2023 time series ("Lagging") while about 9 percent of beneficiaries live in HRRs with ACO penetration 10 percentage points or more above the national average over the same period ("Leading"). Relative to the 2011 base year immediately preceding the Shared Savings Program's introduction, growth in average unadjusted per capita spending in 2023 for Lagging and Leading markets was 4.3 percent higher and 3.9 percent lower than the national average. The divergence in spending growth was even wider after HCC risk adjustment: 5.3 percent higher for Lagging markets and 4.6 percent lower for Leading markets.

These market trends potentially overstate the impact that ACOs may have had on program spending in 2023. The portion of the difference in spending growth driven by risk adjustment may reflect efforts by ACOs to increase coding intensity. Leading markets may exhibit higher participation rates in CMMI models. ACO participation may naturally flock to markets with lower trend for exogenous reasons. Still, conservatively assuming only 35 percent of the unadjusted trend gap is causally related to Shared Savings Program ACOs would roughly validate the $5.2 billion gross savings indicated by comparing aggregate program benchmarks to actual ACO spending in 2023, and the roughly $2 billion in

net savings to FFS Medicare. A more optimistic estimate, assuming Shared Savings Program ACOs were responsible for 50 percent of the risk-adjusted spending growth difference (mirroring assumptions used in the December 2018 final rule), would imply net savings roughly 3 times greater, or roughly $6 billion net savings for FFS Medicare.

In the CY 2026 PFS proposed rule (90 FR 32815 through 32816), we explained that a study of benchmark performance for cohorts of ACOs that participated in both performance year 2022 and performance year 2023 (with related details in Table D-B10) reveals that the BASIC track is the primary driver of net savings (as measured by program benchmark target spending less actual spending and shared savings payments). Twenty-five ACOs moved from a one-sided model of the BASIC track (Level A or B) to a two-sided model of the BASIC track (Level C, D or E) over performance year 2022 to 2023 and showed the highest rates of net savings to the program at 2.4 percent of benchmark. One hundred six ACOs remained in two-sided models of the BASIC track (Levels C, D or E) over that same 2-year period and reached 2.3 percent net savings. Both cohorts showed the lowest average unadjusted per capita spending trend over this 2-year period at about 6 percent. One hundred thirty-nine ACOs remained in one-sided models of the BASIC track (Level A or B) over both years and saw net savings grow from 1.4 percent to 1.7 percent by 2023. The 135 ACOs that remained in the ENHANCED track over these 2 years showed 1.3 percent net savings in 2023, up slightly from 1.2 percent for 2022. Findings are compared for each cohort in the study in Table D-B10.

TABLE D-B10: WEIGHTED AVERAGE FINANCIAL PERFORMANCE BY ACO COHORT DEFINED BY PATH OF PARTICIPATION OVER PY 2022 TO PY 2023 ($ BILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

Participation Pathway From PY22 to PY23	ACO Count	Benchmark ($B) [A]	Gross Savings % of Benchmark [B]		Shared Savings % of Benchmark [C]		Net Difference % of Benchmark [D]		Unadjusted Per Capita Spending Growth 2022 to 2023 [E]
			2022	2023	2022	2023	2022	2023	
BASIC AB->AB	139	34	-2.2%	-2.7%	0.8%	1.0%	-1.4%	-1.7%	1.08
BASIC AB->CDE	25	5	-4.3%	-4.4%	1.6%	2.1%	-2.7%	-2.4%	1.06
BASIC CDE->CDE	106	26	-3.8%	-4.4%	1.8%	2.2%	-2.0%	-2.3%	1.06
BASIC->ENHANCED	10	5	-5.0%	-6.9%	2.2%	5.1%	-2.8%	-1.8%	1.13
ENHANCED->ENHANCED	135	48	-4.6%	-5.0%	3.4%	3.7%	-1.2%	-1.3%	1.07

Notes: "Participation Pathway" are the following groups of ACOs, identified by the track/level of their participation in PY 2022 and PY 2023: "BASIC AB->AB" are ACOs that remained in a one-sided model of the BASIC track (Level A or B) for PY 2022 and PY 2023; "BASIC AB->CDE" are ACOs that participated in a one-sided model of the BASIC track (Level A or B) for PY 2022, and advanced to a two-sided model of the BASIC track (Level C, D, or E) for PY 2023; "BASIC CDE->CDE" are ACOs that remained in two-sided models of the BASIC track (Levels C, D or E) for PY 2022 and PY 2023; "BASIC->ENHANCED" are ACOs that participated in the BASIC track in PY 2022, and entered a new agreement period to participate in the

ENHANCED track for PY 2023; and "ENHANCED->ENHANCED" are ACOs that remained in the ENHANCED track for PY 2022 and PY 2023.
"Benchmark" [A] is the total PY 2023 benchmark spending for each cohort, in billions of dollars.
"Gross Savings % of Benchmark" [B] is the percentage that a cohort's combined spending deviated from their combined benchmark spending (a negative percentage implies savings).
"Shared Savings % of Benchmark" [C] is the cohort's combined shared savings (and losses) paid to (from) ACOs expressed as a percentage of benchmark.
"Net Difference % of Benchmark" [D] is the sum of "Gross Savings % of Benchmark" [B] and "Shared Savings % of Benchmark" [C] and represents the portion of gross savings (as measured by program benchmarks) retained by the program.
"Unadjusted Per Capita Spending Growth 2022 to 2023" [E] is the combined average per capita spending for the cohort in 2023 divided by the corresponding average for the same cohort in 2022.

We will continue to study program data as it emerges, including the extent that new ACOs serving higher spending populations of beneficiaries enter the program and drive down spending in the BASIC track, and whether ACOs with lower relative spending migrating to the ENHANCED track are able to demonstrate materially lower spending trend after multiple years under that higher incentive arrangement.

Two changes to Shared Savings Program policies, described in section III.F. of this final rule, are estimated to have a material impact on overall program spending. First, we anticipate that there may be an incremental cost to allowing only 5 performance years in a one-sided model (down from 7 performance years under the current regulations) for ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, with no prior participation in the Shared Savings Program, entering an agreement period beginning on or after January 1, 2027. The cost would depend on the frequency that the extra 2 performance years in a one-sided model would have proven essential for certain ACOs serving higher-cost populations of beneficiaries to transition to performance-based risk and remain in the Shared Savings Program for multiple agreement periods. We have already implemented Shared Savings Program changes to increase participation from this general type of ACO, including ending negative regional adjustments to benchmarks, implementing the health equity benchmark adjustment (in this final rule being renamed "population adjustment"), and providing a prior savings adjustment to the rebased benchmark. However, some ACOs remaining under a one-sided model throughout their first agreement period would likely face significant uncertainty in predicting how these policies may or may not help provide margin for their rebased benchmark at the start of a potential second agreement period. Some such ACOs may find that uncertainty an insurmountable hurdle to renewing their participation in the Shared Savings Program directly into performance-based risk in the first year of their second agreement period. On the other hand, there is a potential for improved care management and increased savings from

other ACOs that successfully manage the transition to performance-based risk earlier than they would have, if they had access to 7 performance years instead of 5 performance years of one-sided model participation in the Shared Savings Program. On net, we project the eventual termination of participation by some ACOs will involve a marginally greater reduction in program savings compared to the potential increase in efficiency from earlier transition to performance-based risk from other ACOs, leading to $370 million higher spending over 10 years, ranging from $50 million lower spending to $920 million higher spending at the 10th and 90th percentiles, respectively. The annual and 10-year total projections for the changes to Shared Savings Program participation options are detailed in Table D-B11.

TABLE D-B11: PROJECTED IMPACT OF REDUCING NEW AND RISK INEXPERIENCED ACOS ELIGIBILITY TO 5 YEARS FROM THE CURRENT 7 YEARS ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	Total
Impact Estimate	0	0	0	0	20	40	80	90	70	70	**370**
Estimate Range:											
Low Estimate (10th Percentile)	0	-10	-20	-40	-40	-20	0	0	10	10	**-50**
High Estimate (90th Percentile)	0	10	10	50	80	130	180	200	160	140	**920**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The second area of material impact on program spending is from the policies to allow ACOs to enter a new agreement period in the BASIC track when an ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, in combination with capping the shared savings or shared losses at a lesser amount for ACOs with fewer than 5,000 assigned beneficiaries in any of the three benchmark years. These policies are expected to marginally increase participation by ACOs that would have otherwise been unable to satisfy the 5,000 assigned beneficiary minimum in BY1, BY2, or both, and to do so under an alternative cap that provides a safeguard against excessive payments if assignment were to grow dramatically during the agreement period despite very low assignment in one or more benchmark years. The alternative cap is also anticipated to generate savings from ACOs that would have otherwise changed composition during the agreement period and exhibited reduced assignment in 1 or more benchmark years in ways that could have produced excessive shared savings payments due to random variation. The annual and 10-year total projections for these provisions are detailed in Table D-B12.

TABLE D-B12: PROJECTED IMPACT FOR ALLOWING ACOS TO ENTER NEW AGREEMENT PERIOD DESPITE EITHER BY1 AND/OR BY2 ASSIGNMENT BELOW 5,000 COMBINED WITH ALTERNATIVE CAP ON SHARED SAVINGS / SHARED LOSSES FOR ACOS WITH FEWER THAN 5,000 ASSIGNED BENEFICIARIES IN ANY BY ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	Total
Impact Estimate	0	0	−10	−10	−30	−50	−70	−80	−70	−70	**−390**
Estimate Range:											
Low Estimate (10th Percentile)	0	−10	−10	−30	−50	−90	−100	−120	−100	−110	**−540**
High Estimate (90th Percentile)	0	0	0	0	−10	−30	−30	−40	−40	−40	**−250**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The remaining changes to the Shared Savings Program regulations, as described in section VI.A.2.e. of this final rule, are not estimated to have an impact on program spending at the aggregate level.

The combined impacts for all Shared Savings Program provisions are shown in Table D-B13. Because estimates are rounded to the nearest $10 million, and because the percentiles are independently sorted for each year and for the 10-year totals, the annual estimates may not sum to exactly match the total 10-year estimates.

TABLE D-B13: PROJECTED IMPACT OF MEDICARE SHARED SAVINGS PROGRAM PROVISIONS (INDIVIDUALLY SHOWN IN TABLES D-B11 AND D-B12) ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	Total
Impact Estimate	0	0	-10	-10	-10	-10	10	10	0	0	**-20**
Estimate Range:											
Low Estimate (10th Percentile)	0	−20	−30	−70	−90	−110	−100	−120	−90	−100	**−590**
High Estimate (90th Percentile)	0	10	10	50	70	100	150	160	120	100	**670**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

b. Compliance with Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the new policies adopted in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: changes to the requirements for ACOs' progression to performance-based risk under the program's participation options (described in section III.F.2. of this final rule); potentially applying an alternative loss recoupment limit, in conducting financial reconciliation for each performance year, for an

ACO with fewer than 5,000 assigned beneficiaries in any BY, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c. of this final rule); excluding ACOs that fall below 5,000 assigned beneficiaries in any BY from being eligible to benefit from the policies providing certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings, for agreement periods beginning on or after January 1, 2027 (described in section III.F.4.c. of this final rule); and mitigating shared losses for an ACO determined to be affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program, for performance year 2025 and subsequent performance years (described in section III.F.7.c. of this final rule). When considered together, these changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by hastening the transition to performance-based risk while improving protections against excessive liabilities both for shared losses charged to participants and shared savings paid by the program. These changes are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule, we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that we have enacted relying on section 1899(i)(3) of the Act as authority (*see* 87 FR 70195 and 70196). The marginal impact of the changes in the CY 2024 PFS final rule were estimated to lower net spending by $330 million over the subsequent 10-year period for all new policies combined, including the cap an ACO's regional service area risk score growth, the addition of a new third step to the beneficiary assignment methodology, and the revised approach to identify the assignable beneficiary population (88 FR 79496). The marginal impact of the changes in the CY 2025 PFS final rule were estimated to lower net spending by an additional $200 million in total through 2034 (89 FR 98527). The marginal impact of the changes in this final rule is estimated to be a $20 million reduction in net spending. The cumulative impact of all policies (including those in this final rule) is estimated to result in more than $4.9 billion in

greater program savings compared to a hypothetical baseline payment methodology that excludes the policies we have enacted relying on section 1899(i)(3) of the Act as authority. Therefore, we estimate that program expenditures associated with the implementation of the provisions in this final rule, in combination with other policies associated with the statutory payment model and current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program and would not be expected to increase program expenditures relative to those of the statutory payment model.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. Additional Shared Savings Program data beginning to accumulate after the end of the PHE for COVID-19, along with emerging information on the characteristics of, and performance trends for, new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024, and January 1, 2025, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

We did not receive public comments on this section, and therefore, we are finalizing as proposed.

7. Changes to the Regulations Associated with the Ambulance Fee Schedule

As outlined in section III.G. of this final rule, section 3203 of the American Relief Act of 2025 and most recently, section 2203 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons sets forth in those sections through September 30, 2025. The ambulance extender provisions are enacted through legislation that is self-implementing. We proposed to revise dates at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions. We have estimated the cost of these

provisions to be $20 million in FY 2025 and $10 million in FY 2026 and the Congressional Budget Office (CBO)'s estimated cost of these provisions was $36 million in FY 2025 and $27 million in FY 2025 to 2029 *(https://www.cbo.gov/system/files/2025-03/hr1968.pdf, page 4)*.

We did not receive any public comments on the impacts of the ambulance extender provisions. Therefore, in this final rule, we are finalizing our proposals to codify our regulations at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these statutory requirements.

8. Updates to the Quality Payment Program

In this section of this final rule, we estimated the impacts of the Quality Payment Program policies. We estimated participation, final scores, and payment adjustments for eligible clinicians participating through MIPS, and the Advanced APMs, and MVPs. We also presented the impacts on the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our proposed policies, relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall Impact Modeling Approach and Data Assessment

(1) MIPS Impact Modeling Approach

For this final rule, we used a similar modeling approach as the CY 2025 PFS final rule (89 FR 97710 through 99057). We created two MIPS impact models: a baseline and a proposed policy model. Our baseline model includes previously finalized policies that are in effect for the CY 2025 performance period/2027 MIPS payment year and in the absence of any of the new policies in this final rule. Examples of previously finalized policies included in the baseline model are updated QP and partial QP thresholds and the previously finalized list of MVPs. Please refer to CY2025 PFS final rule for a comprehensive, detailed discussion of finalized policies (89 FR 97710).

The policies model builds on the baseline model and incorporates the new MIPS policies we are proposing for the CY 2026 performance period/2028 MIPS payment year included in this final rule. By comparing the baseline model to the proposed policies model, we are able to estimate the impact of the specific policies in this final rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This approach enables our model to align as much as possible with actual MIPS scoring and

minimize differences between our projections and actual policy implementation. Our model's limitations are outlined later in this impact analysis.

(2) Data Used to Estimate Future MIPS Performance

In the CY 2025 PFS final rule (89 FR 98531), we explained our decision to use CY 2022 performance period submissions data. We noted that using CY 2022 performance data presents the most current data and aligns participation, final scoring, and payment adjustment analysis around the same common data set. For this final rule, CY 2023 performance data is the most recently available data for us to construct a model simulation for this final rule.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

Beginning with QP Performance Period 2017 (payment year 2019), through the Medicare Option, eligible clinicians who are determined to have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs are QPs for the applicable QP performance period and the corresponding payment year. In payment years 2019 through 2024, these QPs received a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the base year (the calendar year immediately preceding the payment year). In payment year 2025, eligible clinicians who attained QP status for QP Performance Period 2023 will receive a lump-sum APM Incentive Payment equal to 3.5 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. In payment year 2026, eligible clinicians who attained QP status in QP Performance Period 2024 will receive a lump-sum APM Incentive Payment equal to 1.88 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2025.

Beginning with QP Performance Period 2019 (payment year 2021), in addition to the Medicare Option, the All-Payer Combination Option also affords eligible clinicians an opportunity at QP status. The All-Payer Combination Option allows eligible clinicians to become QPs by assessing a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a given QP Performance Period are not subject to MIPS reporting requirements and payment adjustments for the contemporaneous MIPS performance period/payment

year. Eligible clinicians who do not become QPs but who meet a lower threshold requirement to become Partial QPs for the year may elect whether or not to report to MIPS. If they elect to report, they are scored in and receive a payment adjustment under MIPS. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Separately from the APM Incentive Payment, beginning in payment year 2026, there are two separate PFS CFs—one for eligible clinicians who are QPs for the year (the qualifying APM CF), and the other for all non-QP eligible clinicians and other suppliers paid under the PFS (the non-qualifying APM CF). The update to the qualifying APM CF for a year is 0.75 percent, whereas the update to the non-qualifying APM CF for a year is 0.25 percent. For payment year 2026, under current law, both an APM Incentive Payment and the qualifying APM CF will apply. This means that eligible clinicians who attained QP status for QP Performance Period 2024 will receive a lump-sum payment of 1.88 percent of their 2025 covered professional services paid claims as described above, and additionally their 2026 covered professional services claims will be paid using the physician fee schedule rates that are established for the qualifying APM CF.

The thresholds to achieve QP status in the 2026 QP Performance Period (2028 payment year) are set to 75 percent for the payment amount, and 50 percent for the patient count. Overall, we estimated that for the 2026 QP Performance Period, between 375,000 and 482,200 eligible clinicians will become QPs, and therefore will be excluded from MIPS reporting requirements and payment adjustments.

In section IV.A.4.m.(2) of the CY2026 PFS proposed rule, we proposed to modify the definition of "attribution-eligible beneficiary" to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. We are finalizing this proposal with modification to include a methodology that continues to use E/M services and a methodology using covered professional serv ices. Additionally, we are finalizing our proposal to add a QP determination at the individual level for all Advanced APM participants, beginning with the 2026 QP Performance Period.

We projected the number of eligible clinicians who will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2026 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2026 QP Performance Period. The projections also reflect an estimated number of eligible clinicians who will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2026 QP Performance Period:

- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model
- Enhancing Oncology Model (EOM);
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track); and
- Transforming Episode Accountability Model (TEAM)

We used the Participation Lists and Affiliated Practitioner Lists, as applicable (see § 414.1425(a) for information on the APM Participant Lists used for QP determinations) for the 2024 QP performance period third snapshot QP determination date to estimate the number of QPs for the 2026 QP Performance Period. For models starting in the 2026 QP Performance Period we estimated performance based on projected participation. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries were attribution eligible through the APM Entity.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2026 Performance Period/2028 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Proposed Policies Models

For this final rule, we applied the same assumptions as in the CY 2025 PFS final rule (89 FR 98532) to estimate our initial population of clinicians using 2023 performance data. Specifically, we used the CY 2023 final reconciled eligibility determination file, same as the 2022 file described in the CY 2025

PFS final rule (88 FR 79505). This file reconciles eligibility from two determination periods and aligns with the CY 2023 performance period submissions data on which we based this model. Our analysis included 1,889,733 clinicians with PFS claims in this initial population. This initial population of clinicians was used to determine eligibility using the methodology described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians after Applying Eligibility Assumptions

(a) Methods and Assumptions Used to Estimate Eligibility

After identifying the clinician population with PFS claims, we applied the same eligibility assumptions and determination process described in the CY 2025 PFS final rule (89 FR 97710). We did not proposed any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and proposed policies model.

For our impact analysis model, we established the "required eligibility" category, which means the clinician exceeds the low-volume threshold in all 3 criteria (§§ 414.1305 and 414.1310(b)(1)(iii)) and is subject to a MIPS payment adjustment. We based this estimate on the CY 2023 performance period data described in this section of this final rule, which includes the 3 low volume criteria. Within the eligible clinicians, we divided them into two groups- clinicians who report MIPS data and clinicians who do not report MIPS data.

Our next two eligibility assumptions concern clinicians in groups, who may voluntarily participate in MIPS, but are not required to participate. First, we estimate group eligibility. These are the clinicians who have a group submission, and their group exceeds the low-volume threshold in all 3 criteria. Next, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in at least one criterion, but not all three, may elect to opt in. Based on the number of individuals who opted in to MIPS for the CY 2023 performance period/2025 MIPS payment year, our model estimates that these clinicians will continue to opt in to MIPS.

After applying the process outlined in this section of this final rule, we then estimate the number of "Potentially MIPS Eligible" clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These clinicians are potentially eligible; however, they do not choose to report to MIPS

Finally, we estimated the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. First, we estimated the number of clinicians who are below all 3 low-volume criteria (both as an individual and as a group) using the CY 2023 performance data as outlined in this section of this final rule.

Next, we estimated the number of QPs (not MIPS eligible). Also in this final rule, we estimated a range of QPs. For the purposes of our impact analysis, we estimate a specific number of QPs because a specific number of clinicians is needed to simulate the impacts of our proposed policies on participation, final scores, and payment adjustments. Finally, we estimate the number of clinicians who are excluded for other reasons, for example, they are in a clinician type that is not MIPS eligible or newly enrolled in Medicare.

After applying these assumptions to our initial population, we estimate that there will be 607,419 MIPS eligible clinicians with ~$51.84 billion in allowed charges in CY2026.

(b) MIPS Eligibility Estimates

For the impact analysis, we use the estimated population of 607,419 MIPS eligible clinicians described previously in this section of this final rule. Table D-B14 summarizes our eligibility estimates for the policies model after applying our assumptions outlined in this section of this final rule.

TABLE D-B14: ESTIMATION OF MIPS ELIGIBILITY STATUS FOR CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR USING THE CY 2026 PFS FINAL RULE ASSUMPTIONS**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians *	Number of Clinicians	PFS allowed charges ($ in mil)**
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	98,485	$28,689
MIPS eligible	Did not Report to MIPS	38,784	$11,172
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	465,291	$11,705
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	4,812	$275
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**607,419**	**$51,843**
Not MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	176,052	$5,484
Potentially MIPS Eligible	Group Eligible; Did not Report	472,842	$10,966
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	130,002	$810
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	62,084	$549
Qualified Participant (QP)***	Not applicable	441,334	$20,836
Total Number of Clinicians Not MIPS Eligible		1,282,314	**$38,644**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,**889,733**	**$90,487**

* Participation excludes facility-based clinicians who do not have scores in the 2023 MIPS submission data.
** Allowed charges estimated in 2023 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VII.I.5.b. of this final rule because, for purposes of establishing the population used in our modeling, we estimate an absolute number of QPs rather than a range.

We did not have proposals related to applying Eligibility Assumptions.

d. Modeling Approach and Methods for MIPS Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this final rule, we present several proposals that impact the measures and activities, the performance category scores, final scores, and MIPS payment adjustments for MIPS eligible clinicians. In section VII.I.5.d(3). of this final rule, we outline these changes in more detail and describe our methodology to estimate MIPS payment adjustments for the CY 2026 performance period/2028 MIPS

payment year. We then present the impact of the policies in the CY 2026 performance period/2028 MIPS payment year and compare select metrics to the baseline model. By comparing model outputs in the baseline model to the proposed policies model, we are able to observe the impact of the policies for the CY 2026 performance period/2028 MIPS payment year.

MIPS eligible clinicians' final scores are calculated based on the clinicians' performance on measures and activities specified under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the four MIPS performance categories as an individual, group, virtual group, APM Entity and via traditional MIPS, the APM Performance Pathway (APP), or MVP reporting options. MIPS APM participants can participate in the APP as an individual, group, virtual group, or APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. Our simulation applies the proposed and baseline policies to the existing MIPS scoring engine.

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MIPS Value Pathways beginning in the CY 2023 performance period/2025 MIPS payment year.

(2) Methodology to Assess Impact for MIPS Value Pathways

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. We assessed whether to use CY 2024 MVP registration data to estimate MVP participation and policy impact, but elected not to simulate the impact for MVP because we do not presently have sufficient MVP scoring data for modeling and simulation, as we only have 1 year of MVP data from the CY 2023 performance period/2025 MIPS payment year. Our model is based on CY 2023 performance data, which contains only 1 year of MVP scores, and this is insufficient for conducting reconciliation between multiple years, which introduces uncertainty and complexity into our model. As more MVP scoring data becomes available in the future, we will reassess our methodology for estimating MVP participation, final scores, and payment adjustments.

(3) Methodology to Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we generally use the CY 2023 performance data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2026 performance period/2028 MIPS payment year for the baseline and policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, improvement activities, and Promoting Interoperability performance categories, and the application of our final scoring policies.

(a) Methodology to Estimate the Quality Performance Category Score

We used the CY 2025 PFS final rule final policies model as the starting point of our baseline model. Since there are no previously finalized policies impacting the quality performance category that were not already included in the CY 2024 PFS final rule policies model, we did not make any modifications to the quality performance category and the baseline model is identical to the CY 2025 PFS final rules policies model with respect to the quality category.

Our policies model incorporates the following policies from this final rule as outlined in section IV.B. of this final rule:

● In section IV.B.1.a.(2)(a) of this final rule, to facilitate fairer scoring, we proposed to remove the scoring cap and change the benchmarking approach for certain topped out measures applicable to clinicians facing both limited measure choice and limited scoring opportunities. We did not simulate the addition of quality measures described in section IV.A.4.d.(1)(c)(i) of this final rule since we use existing quality measure data from the CY 2023 performance period, which does not include new measures. We did not simulate the removal of quality measures described in section IV.A.4.d.(1)(c)(ii) of this final rule since we cannot predict how clinician behavior and measure selection will change in response.

● In section IV.B.1.a.(2(b)(3) of this final rule, we proposed to modify the methodology for scoring the administrative claims-based measures within the quality performance category. The proposed administrative claims-based quality measure scoring methodology will be based on the standard deviation, the median, and an achievement point value that is derived from the performance threshold.

Specifically, for a MIPS eligible clinician whose performance rate under an administrative claims-based measure will be equal to the median performance rate for all MIPS eligible clinicians that are scored on that measure, we will assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2026 performance period/2028 MIPS payment year, the median would have an achievement point value of 7.5, based on a performance threshold of 75 points as proposed in section IV.B.2.b.(2) of this final rule. For each administrative claims-based quality measure, the cut-offs for benchmark ranges would be calculated based on standard deviations from the median. This policy is incorporated into our model based on the specifications explained in section IV.B.1.a.(2(b)(3) of this final rule.

(b) Methodology to Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2025 PFS final rule (89 FR 98531) for the baseline and the proposed policies RIA models with the modifications described later in this section.

For this final rule, the baseline policies RIA model used the same methodology as the final policies RIA model in the CY 2025 PFS final rule (89 FR 98530). The policies RIA model incorporated and implemented the following changes:

- In section IV.A.4.(d).(2).(c). of this final rule, we proposed to modify the Total Per Capita Cost (TPCC) measure. We also proposed to update the operational list of care episodes and patient condition groups and codes to reflect coding changes identified through our annual maintenance process for MIPS cost measures. We incorporated measures test data with the specifications for the modified measures.
- In section IV.A.4.(d).(2).(d). of this final rule, we proposed to adopt a 2-year informational-only feedback period for newly implemented MIPS cost measures, which we also proposed to codify at § 414.1380(b)(2).

(c) Methodology to Estimate the Promoting Interoperability Performance Category Score

In section IV.A.4.d.(4). of this final rule, we proposed modifications to 2 measures and the adoption of one new optional bonus measure: Public Health Reporting Under TEFCA Measure. However, we did not estimate Promoting Interoperability performance category score impacts because, after conducting an assessment of the proposed policies, we determined that there is insufficient data to model

the impact of adding a new, optional bonus measure on the Promoting Interoperability performance category scores, and therefore, did not incorporate it into our model.

(d) Methodology to Estimate the Improvement Activities Performance Category Score

For the baseline and policies model we used the same method to estimate the improvement activities performance category score as described in the CY 2025 PFS final rule (89 FR 79508) including alignment with the clarification provided regarding IA automatic weighting for APM participants (89 FR 79366).

In section IV.A.4.d.(3).(b). of this final rule, we proposed to amend at § 414.1355(c)(7) by adding a new subcategory, "Advancing Health and Wellness" (AHW), to replace the "Achieving Health Equity" subcategory. We proposed adding three new Improvement Activities while removing eight existing ones. However, the 3 new measures were not included in the RIA model because we lack historical benchmark data to estimate their potential impact. Additionally, the 8 measures being removed were also excluded from the RIA model, as the models cannot predict how clinicians will alter their behavior once these measures are removed.

(e) Methodology to Estimate the Complex Patient Bonus Points

This final rule does not include proposals to modify the complex patient bonus. Therefore, for the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(f) Methodology to Estimate the Final Score

We did not propose any changes to how we calculate the MIPS final score. Our baseline and proposed policies models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For both models, after adding any applicable complex patient bonus, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a MIPS eligible clinician was approved for reweighting of one or more performance category to zero percent of their final score, and the category's weight redistributed to other performance category(ies), for the CY 2023 performance period/2025 MIPS payment year (which was the data source used in our model) in accordance with our reweighting policies under § 414.1380(c)(2), then we continue to apply that reweighting in our model by assigning them a neutral score equal to the performance threshold if all categories were reweighted or assigning the applicable weights to the categories which were reweighted.

Although it is unlikely (but possible) that the exact same clinicians will apply for and receive reweighting in both the CY 2023 performance period/2025 MIPS payment year (which our data is based on) and the CY 2026 performance period/2028 MIPS payment year (which we are simulating), we believe that this assumption accurately reflects future clinician behavior for two reasons. First, while the exact same MIPS eligible clinicians may not receive reweighting in 2 different years, we believe that this assumption allows us to quantify the impact of the reweighting on a population level. In other words, even if the same clinicians do not apply for and receive reweighting in these 2 different years, the absolute number of reweighting and the characteristics of practices that receive reweighting are likely to remain similar. Secondly, if we were to not assign reweighting to those MIPS eligible clinicians, many of them would receive a very low final score because they did not submit data for one or more performance categories during the year in which they received reweighting. We do not believe that it is a realistic assumption that, in the absence of reweighting, those clinicians will continue not to submit data. For these reasons, we assume that clinicians who received reweighting in the CY 2023 performance period/2025 MIPS payment year are also approved for reweighting in the CY 2026 performance period/2028 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this corresponds with a neutral (0 percent) payment adjustment.

(g) Methodology to Estimate the MIPS Payment Adjustment

For the baseline and proposed policies models, we applied the hierarchy as finalized in the CY 2023 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We

then calculate the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we apply the performance threshold of 75 points finalized in the CY 2025 PFS final rule. In section IV.B.2.b.(2) of this final rule, we proposed to again set the performance threshold at 75. Therefore, for both the baseline and proposed policies models we used a performance threshold of 75 to calculate the exchange function used for MIPS payment adjustments. We noted that the results of this exchange are not identical between the baseline and proposed policies models. This is due to the scaling factor used to determine positive adjustments is dependent on the total dollar amount of negative payment adjustments and those adjustments differ as final scores are not identical between both models.

For both the baseline and proposed policies models, we use these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in section VII.I.5.d.(3). of the final rule, we create a baseline and proposed policies simulation. Using this simulation, we estimate the impact of the policies of this final rule.

(a) Impact on Clinician Eligibility

In section VII.E.17.c.(2). of this final rule, we noted that we do not modify clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact on Clinician's Final Scores

Table D-B15 shows the median final score by practice size and the percentage of MIPS eligible clinicians of each practice size with a positive, neutral, or negative adjustment.

TABLE D-B15: CY 2026 FINAL SCORE ESTIMATES BY PRACTICE SIZE

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					

(1) Solo	17,074	75.00	32.88%	17.98%	49.14%
(a) Engaged***	8,131	87.63	68.86%	7.77%	23,37
(b) Non-Reporting****	8,934	21.95	0.11%	27.27%	72.62%
(2) 2 to 15	66,808	87.21	66.19%	12.54%	21.27%
(3) 16 to 99	116,647	87.37	76.37%	7.17%	16.45%
(4) 100+	406,890	88.46	90.68%	1.19%	8.14%
Overall	607,419	87.96	83.61%	4.06%	12.33%
Proposed Policies					
(1) Solo	17,074	75.00	32.85%	17.99%	49.16%
(a) Engaged	8,131	87.70	68.92%	7,76%	23.32%
(b) Non-Reporting	8,943	21.99	0.11%	27.27	72.62%
(2) 2 to 15	66,808	87.53	66.39%	12.57%	21.04%
(3) 16 to 99	116,647	88.32	77.23%	7.06%	15.71%
(4) 100+	406,890	89.89	91.04%	1.18%	7.78%
Overall	607,419	89.47	84.04%	4.03%	11.92%

The median final score includes clinicians who receive reweighting for all MIPS performance categories our policies at § 414.1380(c)(2). These clinicians who have all performance categories reweighted are assigned a score of 75 (neutral payment adjustment) in our model.
*** An engaged clinician refers to a MIPS-eligible clinician who self-reports at least one measure, attestation, or activity.
****A non-reporting clinician was a clinician who was required to report but did not actively self-report at least 1 measure, attestation, or activity.

The overall median final score is 87.96 in our baseline model and 89.47 in our proposed policies model, a slight increase for all practice sizes. There is a slight increase in the percentage of clinicians receiving a positive payment adjustment. We project that, overall, 83.61 percent of MIPS eligible clinicians will receive a positive adjustment in our baseline model, and 84.04 percent of MIPS eligible clinicians will receive a positive adjustment in our policies model. This slight increase is largely due to our proposed policies in the quality category, including the change to the administrative claims based quality measure scoring methodology and the updated topped out measure policy discussed in section IV.B.1.a.(2). of this final rule. Table D-B16 shows the median quality category score for MIPS eligible clinicians who are scored on the quality performance category for our baseline and proposed policies model. There is a noticeable difference in median quality category scores between our two models. This is true across almost all practice sizes, except for solo practitioners. The overall median quality category score is 78.78 in our baseline model and 83.76 in our policies model.

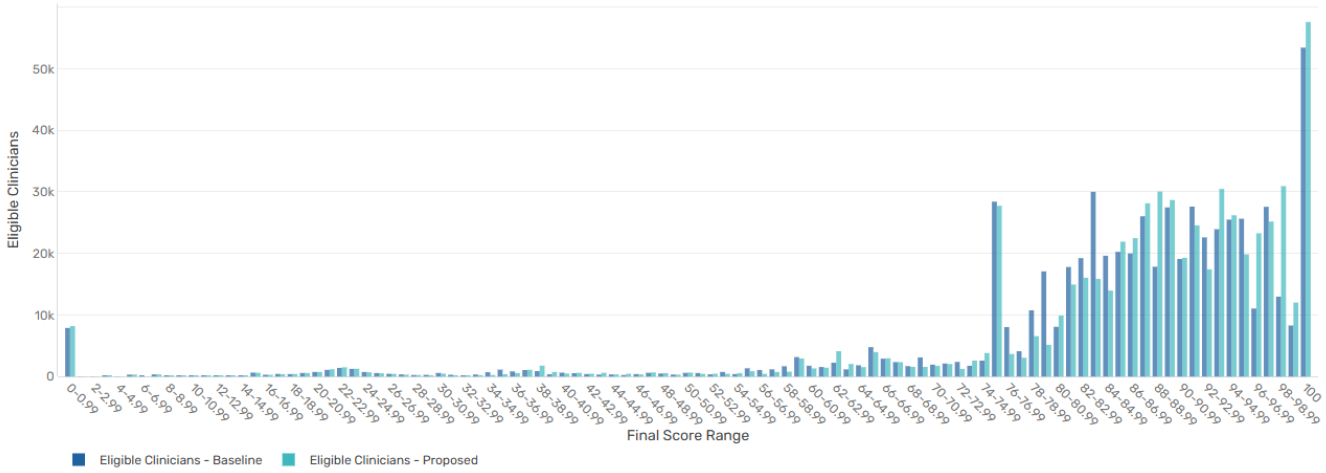
TABLE D-B16: CY 2026 QUALITY SCORE ESTIMATES BY PRACTICE SIZE

Practice Size	MIPS Eligible Clinicians Receiving Quality Score	Total Number of MIPS Eligible Clinicians	Proportion of MIPS Eligible Clinicians Receiving Quality Score	Median Quality Score Estimate
Baseline				
(1) Solo	13,862	17,074	81.19%	29.94%
(a) Engaged*	7,386	8,131	90.62%	82.59%
(b) Non-Reporting**	6,494	8,943	72.62%	0%

(2) 2 to 15	56,708	66,808	84.88%	83.43%
(3) 16 to 99	99,123	116,647	84.98%	80.10%
(4) 100+	381,902	406,890	93.86%	78.47%
Overall	551,595	607,419	90.81%	78.78%
Proposed Policies				
(1) Solo	13,863	17,074	81.19%	29.96%
(a) Engaged	7,369	8,131	90.63%	84.02%
(b) Non-Reporting	6,494	8,943	72.62%	0%
(2) 2 to 15	56,713	66,808	84.89%	84.58%
(3) 16 to 99	99,333	116,647	85.16%	82.44%
(4) 100+	382,671	406,890	94.05%	84.00%
Overall	552,580	607,419	90.97%	83.76%

Figure D-B1 shows the distribution of final scores for all MIPS eligible clinicians. Note that there is a noticeable size of MIPS eligible clinicians with a final score of 75. MIPS eligible clinicians whom we approved for reweighting of all MIPS performance categories in accordance with our reweighting policies at § 414.1380(c)(2) are assigned a final score of exactly the performance threshold (75). Overall, the distribution is left skewed, indicating that many more clinicians would receive final scores on the higher side.

FIGURE D-B1: Count of MIPS Eligible Clinicians by Final Score



(i) Impact to Small and Solo Practices

Solo practitioners account for 17,074 MIPS eligible clinicians or 2.81 percent of all MIPS eligible clinicians in both the baseline and proposed policies models. The median final score for all solo practitioners is exactly equal to the performance threshold (75) in both the baseline and proposed policies model. The portion of all solo practitioners receiving a positive adjustment are almost the same between the baseline and the proposed policies models (32.85 percent baseline vs 32.88 proposed policies).

Solo practitioners have a lower overall median final score than other practice sizes. This is largely due to the fact that many of these solo practitioners do not actively submit data to MIPS despite being MIPS eligible clinicians. Our 2022 analysis indicates that 49.12 percent of solo practitioners submit data to MIPS compared to 94.07 percent of all clinicians. For solo practitioners who submit data, the median final score is 87.63 in the baseline and 87.70 in the proposed policies model. In contrast, those who did not report data to MIPS have a median final score of to 21.95 in the baseline model and 21.99 in the proposed model. These findings indicate that the lower final scores among solo practitioners are likely, and largely, due to not reporting data to MIPS.

Table D-B17 shows that, even among engaged solo practitioners, the percentage receiving a positive payment adjustment is lower than that of clinicians from medium or large practices, while being comparable to those from small practices. Similarly, even for engaged solo practitioners, a higher proportion of them face negative payment adjustments compared to those in other practice sizes. Figure D-B2 shows the distribution of final scores for solo practitioners. Both box plots show similar final score distributions, and both baseline and proposed policies models show a large distance between the lower and upper quartiles. Figure D-B3 shows the final score distribution for all MIPS eligible clinicians between the baseline and the proposed policies models. These models show similar final score distributions, with the proposed policies model showing slightly higher scores. The upper quartile of is 94.25 in the baseline model and 95.82 in the proposed policies model. The distance between lower and upper quartiles is substantially narrower for all MIPS eligible clinicians than it is for solo practitioners. Figure D-B4 shows the distribution of final scores for solo practitioners who actively submit data to MIPS. This distribution is similar to the distribution of final scores in all MIPS eligible clinicians.

Additionally, the upper quartile is at 95.86 in the baseline and at 96.07 in the proposed policies model, which are slightly higher than that for all MIPS eligible clinicians. This suggests that, while many solo practitioners do not submit data to MIPS, those who do submit MIPS data tend to perform comparably to all MIPS eligible clinicians. This further supports the idea that the primary reason for low final scores among solo practitioners is the high number of them who do not submit MIPS data.

FIGURE D-B2: Distribution of Final Scores for Solo Practitioners

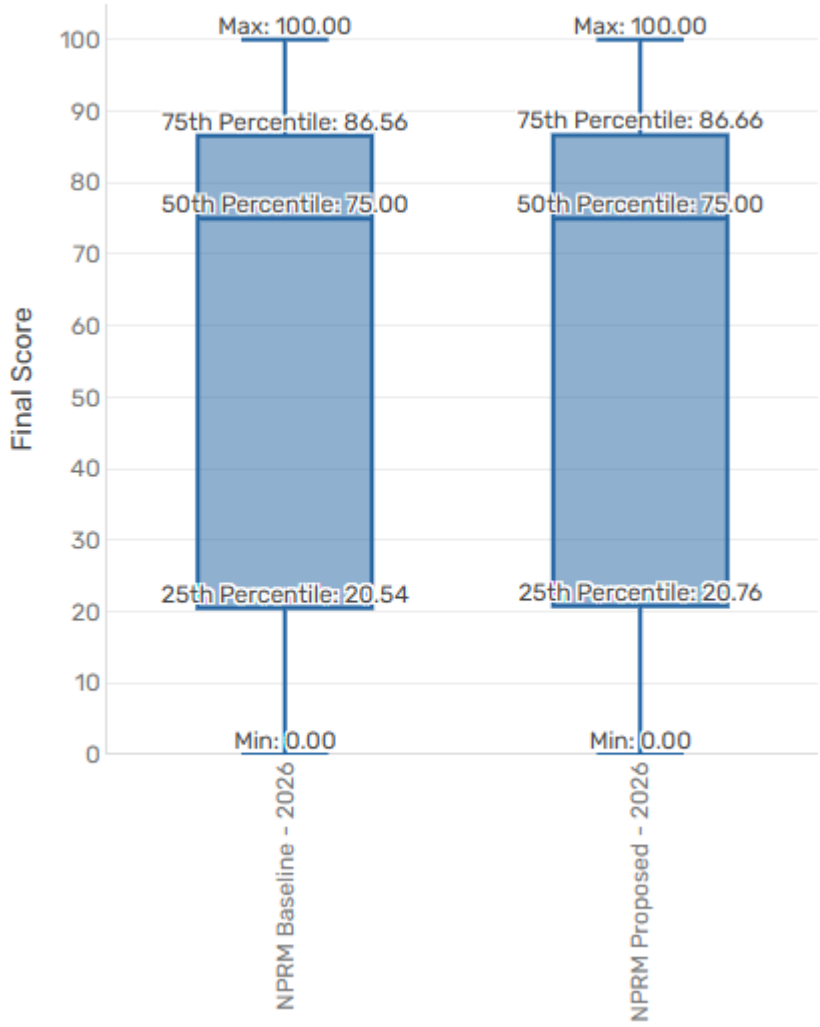


FIGURE D-B3: Distribution of Final Scores for All MIPS Eligible Clinicians

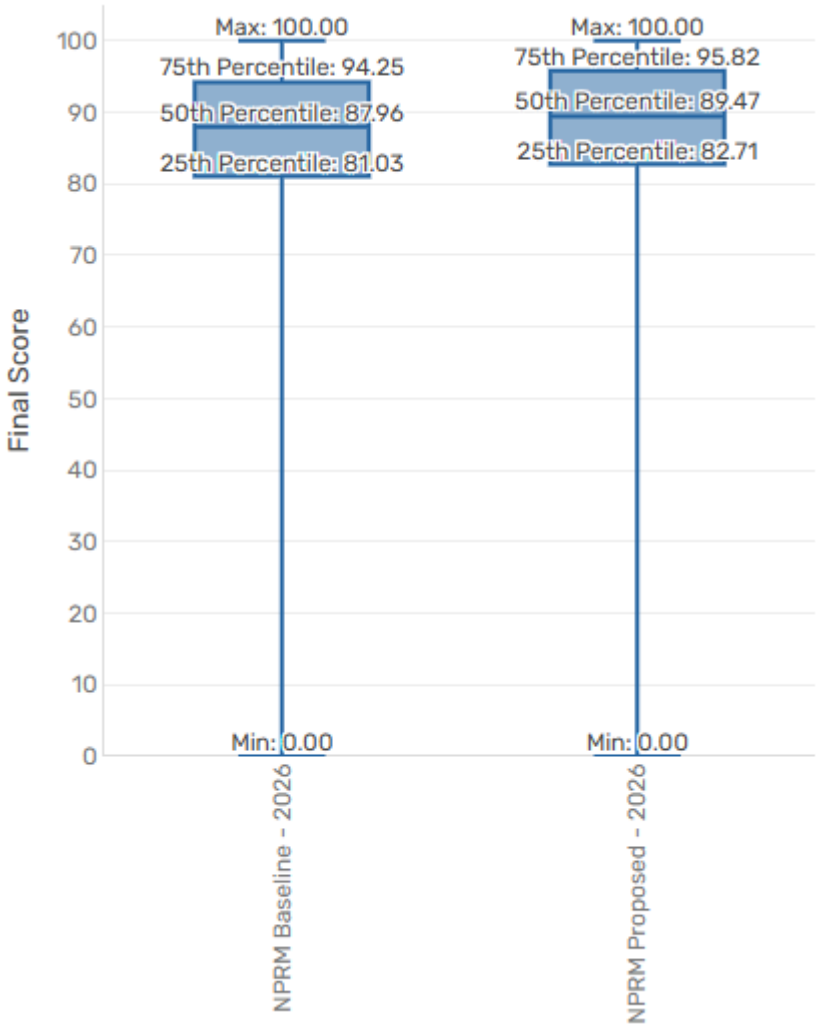
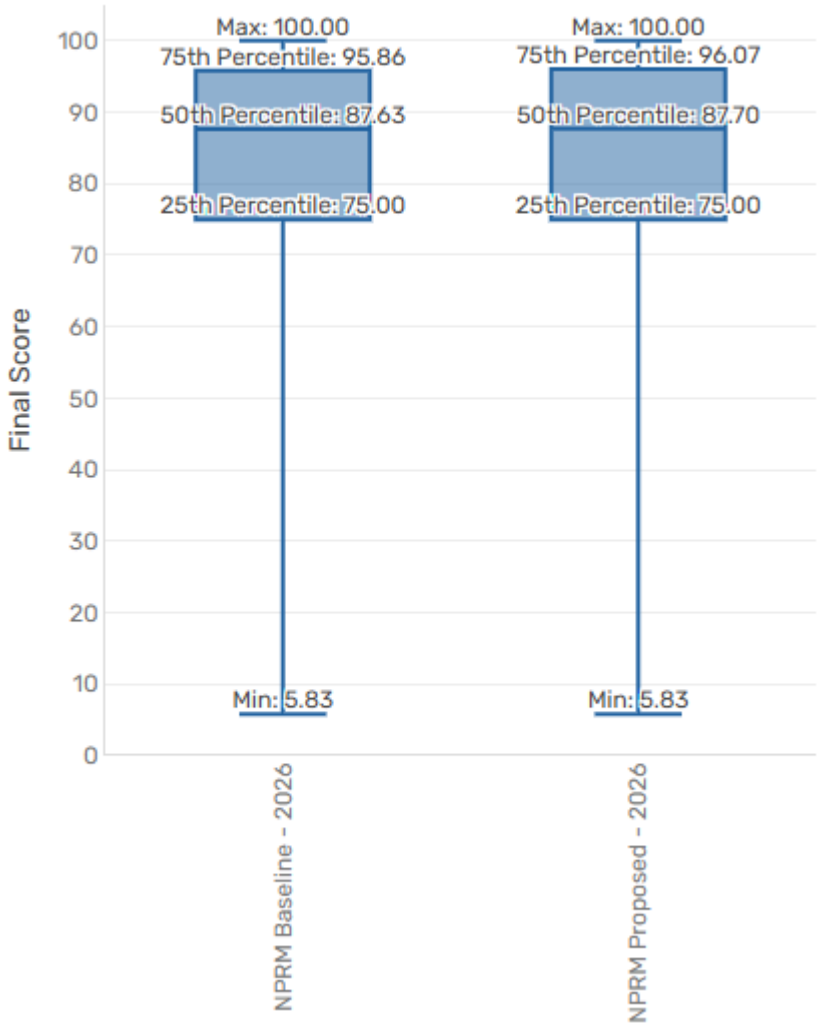


FIGURE D-B4: Distribution of Final Scores for Solo Practitioners who Submit Data



Small practices, defined at § 414.1305 as groups with 2 to 15 clinicians, have a median final score of 87.21 in the baseline and 87.53 in the policies model. This is slightly lower than the overall median final scores of 87.96 in the baseline model and 89.47 in the proposed policies model. Among small practices that submit data (Table D-B17), the median final score is 91.67 in the proposed policies model and 91.23 in the baseline model. They are higher than the median final score for all MIPS eligible clinicians who submit data, which are 90.10 in the proposed policy model and 89 in the baseline model. This indicates that small practices that submit MIPS data perform slightly better than it is for all MIPS eligible clinicians. Table D-B17 shows the percentage of clinicians, by practice size, either do or do not submit data to MIPS and their corresponding median final scores. Note that, in the proposed policies model, the median final scores for medium and large practice clinicians who do not submit data are 75. This indicates that many medium or large practice clinicians who do not submit data to MIPS have been

approved for reweighting of all of their MIPS performance categories under our policies at § 414.1380(c)(2). In contrast, the median final scores for solo and small practice clinicians, who do not submit data are 21.99 and 27.65, respectively. This indicates that many of them are either not being eligible for or not applying for our reweighting policies. Over 90 percent of the medium and large practice clinicians submit data to MIPS. It is possible that the 10 percent or less MIPS eligible clinicians who do not submit data to MIPS are primarily those who have received reweighting under our policies at § 414.1380(c)(2).

TABLE D-B17: PERCENTAGE OF MIPS ELIGIBLE CLINICIANS WHO SUBMIT DATA AND MEDIAN FINAL SCORE

	Percentage of MIPS Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	Median Final Score of MIPS Eligible Clinicians who Do not submit data.
Baseline			
(1) Solo	47.62%	87.63	21.95
(2) Small (2 to15)	79.31%	91.23	28.21
(3) Medium (16 to 99)	90.14%	89.02	75
(4) Large (100+)	98.70%	88.65	75
Overall	93.49%	89.00	75
Proposed Policies			
(1) Solo	47.62%	87.70	21.99
(2) Small (2 to 15)	79.31%	91.67	27.65
(3) Medium (16 to 99)	90.34%	89.91	75
(4) Large (100+)	98.71%	90.06	75
Overall	93.53%	90.10	75

(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Impact assessment of this group of clinicians indicates that their final scores are similar to the overall MIPS eligible clinicians. Table D-B18 shows the median final score and the percentage of eligible clinicians with a positive, neutral, or negative adjustment by practice size for rural practitioners.

TABLE D-B18: CY 2026 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR RURAL PRACTITIONERS ONLY

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	2,306	75.00	37.73%	14.92%	47.35%
(a) Engaged*	1,251	86,78	69.54%	5.36%	25.10%

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
(b) Non-Reporting**	1,055	21.44	0.00%	26.26%	73.73%
(2) 2 to 15	10,112	88.61	71.78%	8.24%	19.99%
(3) 16 to 99	20,427	87.31	79.62%	4.04%	16.34%
(4) 100+	36,288	86.34	90.66%	0.41%	8.93%
Overall	69,133	86.42	82.87%	3.11%	14.02%
Proposed Policies					
(1) Solo	2,306	75.00	37.77%	14.92%	47.31%
(a) Engaged	1,251	86.78	69.62%	5.36%	25.02%
(b) Non-Reporting	1,055	21.57	0.00%	26.26%	73.74%
(2) 2 to 15	10,112	89.11	71.94%	8.24%	19.82%
(3) 16 to 99	20,430	88.63	81.57%	4.06%	14.37%
(4) 100+	36,283	87.74	90.67%	0.40%	8.94%
Overall	69,131	87.80	83.47%	3.11%	13.41%

*An engaged clinician refers to a MIPS-eligible clinician who self-reports at least 1 measure, attestation, or activity.
**A non-reporting clinician was a clinician who was required to report but did not actively self-report at least 1 measure, attestation, or activity.

The overall median final score for rural practitioners is 86.42 in our baseline model and 87.80 in our policies model. This is slightly lower than the median final score for all MIPS eligible clinicians, which is 87.96 in our baseline model and 89.47 in our policies model. According to the results from the proposed policies model, large practice rural clinicians (100+) have a slightly lower median final score (87.74) than it (89.89) is for all MIPS eligible clinicians practicing in large practices.

(iii) Impact to Safety Net Providers

(a) Updated Definition of Safety Net Providers

In the CY 2022 PFS final rule (87 FR 70094), we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

In the 2024 PFS final rule (88 FR 79513), we compared the performance of clinicians who received the complex patient bonus with our overall population. As we further developed our model, we decided to adopt a more precise definition of safety net providers. We believe that by narrowing our definition of safety net providers to clinicians fall in the top 20 percentile for their percent share of

patients who are dually eligible for Medicare and Medicaid, we can identify providers who care for a large proportion of socially vulnerable individuals.

Table D-B19 shows the final score estimates for safety net providers under this new definition. Safety net has higher median final scores (92.43 in the proposed model) than the overall population of MIPS eligible clinicians (89.47 in the proposed model). Safety net solo providers who submit data have a slightly higher median final score (89.66 in the proposed model) than that from the overall solo population who submit data (87.70 in the proposed model). However, only 42.89 percent of safety net solo and 71.14 percent of safety net small practice providers submit data compared to 47.62 percent and 79.31 percent of the overall solo and small practice providers, respectively. Table D-B19.

TABLE D-B19: CY 2026 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR *SAFETY NET PRACTITIONERS ONLY*

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	5,039	57.81	28.70%	16.21%	55.09%
(a) Engaged*	2,161	89.39	66.45%	7.45%	26.10%
(b) Non-Reporting**	2,878	21.89	0.35%	22.79%	76.86%
(2) 2 to 15	13,412	85.49	58.38%	12.79%	28.83%
(3) 16 to 99	29,166	90.33	77.72%	7.08%	15.20%
(4) 100+	81,157	92.06	91.67%	0.95%	7.38%
Overall	128,774	90.96	82.58%	4.17%	13.25%
Proposed Policies					
(1) Solo	5,039	57.76	28.72%	16.19%	55.09%
(a) Engaged	2,161	89.66	66.50%	7.40%	26.10%
(b) Non-Reporting	2,878	21.90	0.35%	22.79%	76.86%
(2) 2 to 15	13,412	85.9	58.64%	12.79%	28.56%
(3) 16 to 99	29,159	91.23	77.66%	7.22%	15.13%
(4) 100+	81,136	93.67	92.29%	0.94%	6.77%
Overall	128,746	92.43	82.98%	4.19%	12.82%

*Engaged clinician refers to a MIPS-eligible clinician who self-reports at least 1 measure, attestation, or activity.
**A non-reporting clinician was a clinician who was required to report but did not actively self-report at least 1 measure, attestation, or activity.

TABLE D-B20: CY 2026 MEDIAN FINAL SCORES FOR *SAFETY NET PRACTITIONERS WHO SUBMIT DATA*

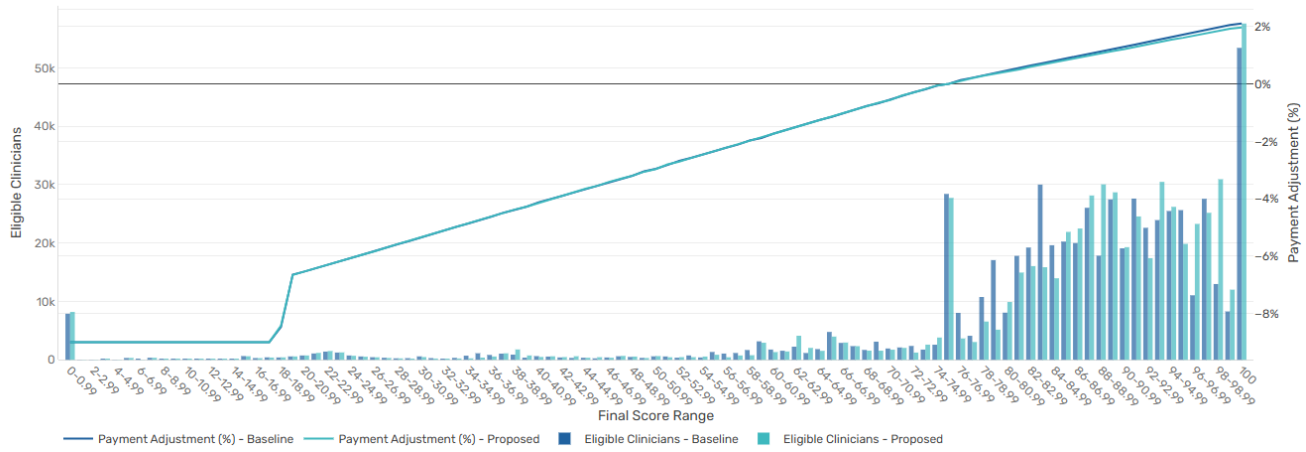
Practice Size	Percent of MIPS Eligible Clinicians who Submit Data	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	42.89%	89.39	66.45%	7.45%	26.10%
(2) 2 to 15	71.14%	93.83	81.95%	3.98%	14.07%
(3) 16 to 99	88.39%	91.63	86.98%	0.43%	12.58%
(4) 100+	98.43%	92.38	92.90%	0.00%	7.09%
Overall	91.14%	92.17	90.23%	0.56%	9.22%
Proposed Policies					
(1) Solo	42.89%	89.66	66.50%	7.40%	26.10%
(2) 2 to 15	71.14%	94.17	82.32%	3.99%	13.69%
(3) 16 to 99	88.52%	92.73	86.77%	0.72%	12.51%
(4) 100+	98.46%	93.99	93.50%	0.00%	6.50%
Overall	91.19%	93.51	90.61%	0.62%	8.77%

(c) Impact to MIPS Eligible Clinicians' Payment Adjustments

We did not proposed to increase the performance threshold in this final rule and did proposed to set the performance threshold at 75 points for a period of 3 years. However, as we get consistent and more data as the program evolves, we will continue to gauge whether the performance threshold should be increased in future years.

Table D-B21 shows that the payment adjustments are very similar between the baseline and proposed policies model. This is because we have made minimal changes to our proposed policies. Although payment adjustments are slightly higher in the baseline model. In the baseline model, we project redistributing $464 million, and in the proposed policies model, we project redistributing $463 million. This decrease is due to the slightly higher proportions of clinicians receiving positive payment adjustments in the proposed policies model (84.05 percent) than it is in the baseline model (83.61 percent). As the proportion of MIPS eligible clinicians receiving a positive payment adjustment increases, the portion of clinicians receiving a negative payment adjustment decreases accordingly (11.92 percent in the proposed policies model vs. 12.33 percent in the baseline model). As the proportion of MIPS eligible clinicians receiving negative payment adjustments decreases, the budget neutral funds available for redistribution also decrease.

FIGURE D-B5: Final Score Distribution and Payment Adjustment



We also report on the median positive and negative payment adjustments by practice size in Table D-B21.

TABLE D-B21: CY 2026 MEDIAN POSITIVE AND NEGATIVE PAYMENT ADJUSTMENT ESTIMATES BY PRACTICE SIZE

Practice Size	Median Positive Payment Adjustment*	Median Negative Payment Adjustment*
Baseline		
Solo (1)	1.52%	-6.58%
(a) Engaged**	1.52%	-3.02%
(b) Non-Reporting***	0.13%	-9.00%
Small (2-15)	1.51%	-5.97%
Medium (16-99)	1.35%	-1.77%
Large (>99)	1.25%	-1.46%
Overall	1.28%	-1.93%
Proposed Policies Model		
Solo (1)	1.44%	-6.55%
(a) Engaged	1.45%	-3.04%
(b) Non-Reporting	0.09%	-9.00%
Small (2-15)	1.44%	-6.08%
Medium (16-99)	1.32%	-1.78%
Large (>99)	1.27%	-1.44%
Overall	1.30%	-1.88%

Final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal to the performance threshold.
**An engaged clinician refers to a MIPS-eligible clinician who self-reports at least 1 measure, attestation, or activity.
***A non-reporting clinician was a clinician who was required to report but did not actively self-report at least 1 measure, attestation, or activity.

The overall median negative payment adjustment in the proposed policies model is slightly lower than it is in the baseline model. That is because the proposed policies model has a higher mean final score than the baseline model (89.47 proposed vs. 87.96 baseline). In Table D-B22, we report the proportion of

MIPS eligible clinicians who either did or did not submit data with the maximum negative adjustment (-9 percent).

e. Additional Impacts from Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting payment adjustments, we are finalizing several policies that will impact burden. In section V.B.5. of this final rule, we separately estimate the burden impacts of finalized policy provisions, and the associated updated data sources. In Table D-B22, we summarize the incremental burden of the finalized policy provisions for these ICRs by year and OMB control number.

TABLE D-B22: INCREMENTAL ESTIMATED BURDEN FROM ASSOCIATED POLICIES

PRA Package(s)	Performance Year	Burden Description and Associated Provisions	Burden Hours	Burden Dollars
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for Traditional MIPS Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR due to the finalized provision of additional MVPs**	(5,510)	($655,228)
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for Traditional MIPS Quality Data Submission by Clinicians: MIPS CQM/QCDR Collection Type ICR due to the finalized provision of additional MVPs**	(7,357)	($901,575)
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for Traditional MIPS Quality Data Submission by Clinicians: eCQM Collection Type ICR due to the finalized provision of additional MVPs**	(8,912)	($1,110,056)
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for MVP registration ICR due to the finalized provision of additional MVPs**	578	$62,227
0938-1314 (CMS-10621)	CY 2026 performance period/ 2028 MIPS payment year*	Annual burden change for MVP Quality Submission ICR submissions due to the finalized provision of additional MVPs**	14,403	$1,763,875
	CY 2026 performance period/ 2028 MIPS payment year*	Annual total change in burden due to policy provisions **	(6,798)	($840,757)
	CY 2026 performance period/ 2028 MIPS payment year	Annual total burden for relevant ICRs***	520,708	$63,731,976
0938-1222 (CMS-10450)	CY 2027 performance period/ 2029 MIPS payment year	Annual burden change for CAHPS for MIPS Vendor Registration due to the finalized provision of the additional web mode**	10	$1,077
0938-1222 (CMS-10450)	CY 2027 performance period/ 2029 MIPS payment year	Annual total burden for relevant ICR***	110	$11,843
	CY 2027 performance period/ 2029 MIPS payment year	Annual total change in burden due to policy provisions**	(6,788)	($839,680)

* Initial performance year affected by this policy. We presume the same annual burden also applies to the CY 2027 performance period/2029 MIPS payment year. Accordingly, these estimates are included in the annual total change in burden for the CY 2027 performance period/2029 MIPS payment year displayed in this table.
** Change in hours relative to estimates for the currently approved under OMB control number 0938-1222 (CMS-10450) and as currently submitted for OMB approval under 0938-1314 (CMS-10621). Change in cost represents change in hours multiplied by the related wage rates.
*** This calculation is the total annual burden estimate for the referenced ICR per control number in this table, inclusive of the currently approved estimates and changes due to both policy and data adjustments.

(2) Additional Impacts to Clinicians

We provide additional burden discussions for policy provisions that we are unable to quantify.

(a) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.4.d(3)(b)(ii) of this final rule, we are finalizing our proposed changes to the Improvement Activities Inventory beginning with the CY 2026 performance period/2028 MIPS payment year. We do not expect these changes to affect our burden estimates for the number of estimated respondents or response time, as most of the improvement activities in the Improvement Activities Inventory remain unchanged for the CY 2026 performance period/2028 MIPS payment year. We refer readers to section IV.A.4.d.(3).(b).(ii). of this final rule for details on the changes to the Improvement Activities Inventory.

(b) Qualifying Alternative Payment Model (APM) Participant (QP) Determinations

In section IV.B.5.b. of this final rule, we are finalizing our proposal to add a QP determination at the individual level for all Advanced APM participants. Additionally, we are finalizing with modification our proposal to update the definition of "attribution-eligible beneficiary" at § 414.1305. We note that year-over-year participation changes have historically had outsized impacts on our projections. For example, ACOs frequently add or remove participants as part of their operations. These changes in participation make it difficult to project how these proposals will impact clinicians who are determined to be QPs, Partial QPs, or previously reported MIPS (at the individual, group, subgroup, or APM Entity level), if at all. Accordingly, we have not adjusted our estimates related to performance category submissions due to these policy provisions. For details on these policies, see section IV.B.5.b. of this final rule. Additionally, we are finalizing our proposal to remove the current 50 clinician limit from the Medical Home Model, the Aligned Other Payer Medical Home Model, and the Medicaid Medical Home model. Where there are no APMs meeting the definition of these three models in the CY 2026 performance period/2028 MIPS payment year, we do not anticipate any reporting impact for these provisions. For details on these policies, see section IV.B.5.c. of this final rule.

(c) Ambulatory Specialty Model

In section III.D. of this final rule, the Innovation Center is finalizing to test a new mandatory model titled the Ambulatory Specialty Model (ASM). The ASM leverages a framework similar to the MVP framework and shares some quality and cost measures with those in the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVP. Review section III.D of

this final rule for additional details on the finalized model requirements and correlation to the existing MVP framework, and impacts of the finalized ASM model.

f. Assumptions & Limitations

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2023 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2026 performance period/2028 MIPS payment year.

As discussed in section V.B.8. of this final rule, we are unable to predict which specific MIPS eligible clinicians will receive reweighting for one or more performance categories under policies at § 414.1380(c)(2) in the CY 2026 performance period/ 2028 MIPS payment rear. On this basis, we assumed that those MIPS eligible clinicians for whom we approved reweighting of one or more performance categories under our policies are representative of the number and attributes of MIPS eligible clinicians who will receive reweighting under these policies in the future.

In addition to the limitations described throughout the methodology sections, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table D-B23.

G. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we exercise agency discretion, presents rationale for our policies, and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to the Use of the Relationship between OPPS APC Payment Rates to Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT codes 77387, 77402, 77407, 77412, and 77417) and Superficial Radiation Treatment (CPT codes 77X05, 77X07, 77X08, and 77X09)

As we discuss in sections II.B and II.E. of this final rule, we proposed to utilize the relationship between OPPS APC payment rates to establish PE RVUs for Radiation Oncology Treatment Delivery and

Superficial Radiation Treatment services. As we considered the most accurate approach to developing PE RVUs for these code families, an alternative we considered was the following approach:

Step 1: Estimate the share of direct costs for all services in the radiology-therapeutic cost center using the hospital cost reports.

Step 2: For each service in an APC, calculate the weighted geometric mean of the OPPS total costs. The weights are PFS non-facility volume.

Step 3: Multiply the result of step 2 by the result of step 1

We did not select this alternative because the use of cost report data to calculate the share of direct costs may reflect an imprecise accounting of direct costs. In addition, the percentage of direct costs is imprecise for a particular service. Therefore, we are unable to confirm the precision of the estimate of the direct costs for these services, which is a necessary step in this calculation. We refer the reader to the RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html*.[483]

2. Alternatives Considered Related to the Use of the Relationship between OPPS APC Payment Rates to Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT codes 77387, 77402, 77407, 77412, and 77417) and Superficial Radiation Treatment (CPT codes 77X05, 77X07, 77X08, and 77X09)

As we discuss in sections II.B. and II.E. of this final rule, we proposed to utilize the relationship between OPPS APC payment rates to establish PE RVUs for Radiation Oncology Treatment Delivery and Superficial Radiation Treatment services. As we considered the most accurate approach to developing PE RVUs for these code families, an alternative we considered was the following approach:

Step 1: Estimate the share of direct costs for all services in the radiology-therapeutic cost center using the hospital cost reports.

Step 2: For each service in an APC, calculate the weighted geometric mean of the OPPS total costs. The weights are PFS non-facility volume.

Step 3: Multiply the result of step 2 by the result of step 1

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[483] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. https://www.rand.org/pubs/research_reports/RR2166.html.

We did not select this alternative because the use of cost report data to calculate the share of direct costs may reflect an imprecise accounting of direct costs. In addition, the percentage of direct costs is imprecise for a particular service. Therefore, we are unable to confirm the precision of the estimate of the direct costs for these services, which is a necessary step in this calculation. We refer the reader to the RAND Corporation (''RAND'') report prepared for CMS, entitled *Practice Expense Methodology and Data Collection Research and Analysis,* available at *https://www.rand.org/pubs/research_reports/RR2166.html*.[484]

3. Alternatives Considered for Adjusting RVUs To Match PE Share in the American Medical Association's (AMA) Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys

As discussed in section II.B. of this final rule, "(5) PE RVU Methodology," Steps 3, 10, and 18, and "3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)", we hold the work RVUs constant and adjust the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the Medicare Economic Index (MEI) cost shares are updated, we would typically proposed to modify steps 3 and 10 described in section II.B. of this final rule to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the updated MEI cost share weights, as previously described in the CY 2014 PFS final rule (78 FR 74236 and 74237), and to recalibrate the relativity adjustment that we apply in step 18 described in section II.B. of this final rule. The most recent recalibration was done for the CY 2014 RVUs. Of note, although we did not propose to for CY 2023, we considered using the rebased and revised 2017-based MEI cost share weights to adjust the aggregate pools of PE RVUs and the relativity adjustment to reflect more recent data, shifting over a 4-year transition to reach the proportions of work, PE, and MP. We refer readers to a detailed discussion of this alternative considered in sections II.B. and V.I. of the CY 2023 PFS final rule

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[484] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. ''Practice Expense Methodology and Data Collection Research and Analysis.'' RAND Corporation, April 11, 2018. https://www.rand.org/pubs/research_reports/RR2166.html.

(87 FR 69414 through 69415 and 70212 through 70217) for awareness regarding potential future rulemaking.

As an alternative to adjusting the aggregate pools of direct and indirect PE costs and using a relativity adjustment based on the currently used 2006-based MEI, we considered three different alternatives related to the weights from the American Medical Association's (AMA) Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys, as discussed in detail in section II.B. of this final rule, for purposes of adjusting the RVUs to match PE share from the surveys for CY 2026:

● Full implementation of the updated PPI and CPI Survey PE/HR data, while maintaining the current cost shares (2006-based MEI) (to allow for isolated comparison to the CY 2025 Final Rule impacts)

● Full implementation of the updated shares, as reported by the AMA, while maintaining the current PE/HR data (to allow for isolated comparison to the CY 2025 final rule impacts)

● Full implementation of updated shares, weighted by Medicare RVUs, while maintaining the current PE/HR data (to allow for isolated comparison to the CY 2025 final rule impacts)

Likely due in part to lower-than-expected response rates, more Medicare specialties were grouped together in the updated PPI and CPI Survey data than the original PPI Survey. The AMA and Mathematica's decision to group together more specialties is a consequential decision alone, therefore, we displayed the estimated specialty-level impacts that would result from mapping the current PE/HR data to the updated specialty groupings reported in the new PPI and CPI Surveys. To do so, we calculated direct and indirect PE/HR values using the existing data (which primarily comes from the 2007-08 PPI Survey) and volume-weighted averages of these existing PE/HR values within each of the new specialty groupings. While this is not an alternative we considered implementing, we believe it is important to display the redistributive impacts of mapping the old PE/HR information to the new specialty groupings for interested parties to consider.

For purposes of displaying impacts for these alternatives considered, we used the estimated impacts from the CY 2025 PFS final rule as a base and comparison rather than the proposed CY 2026 impacts due to the significant redistributive impacts of the policy proposals for CY 2026. We believe that displaying these alternatives considered relative to CY 2025 provides a more stable base to isolate

changes related to the alternatives themselves and allows the public to meaningfully comment on the alternatives considered, as opposed to the interaction of these alternatives with the redistributions attributable to the CY 2026 policy proposals.

Table D-B23 illustrates the estimated specialty-specific impacts under each alternative considered, relative to the CY 2025 PFS final rule estimated impacts as a baseline. The following is an explanation of the information represented in Table D-B23.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2023 utilization and CY 2024 rates. Reminder: CY 2025 Estimated Impacts are used as a baseline for these alternatives considered, therefore, this column matches Column C of Table D-B23 in the CY 2025 PFS final rule (89 FR 98503 through 98507).
- Column D (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges of all the changes finalized for CY 2025. Reminder: this column matches Column D of Table D-B23 in the CY 2025 PFS final rule (89 FR 98503 through 98507).
- Column E (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result from mapping the current PE/HR data to the updated specialty groupings reported in the new PPI and CPI Surveys.
- Column F (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result if we implemented the new PE/HR data from the new PPI and CPI Surveys. Because these changes are solely within practice expense, there would be no impact to the estimated conversion factor and would result only in the redistribution of PE RVUs.
- Column G (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result if we implemented updated cost share weights as reported by the AMA, to adjust the RVUs to match the PE share from the surveys, relative to the impacts for the CY 2025 PFS final rule, while maintaining the current PE/HR data. This results in changes to the work RVU pool, and therefore, yields a different estimated conversion factor.

- Column H (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges that would result if we implemented updated cost share weights derived by CMS from the AMA's PPI and CPI Surveys, weighted by Medicare RVUs, to adjust the RVUs to match the PE share from the surveys, relative to the impacts for the CY 2025 PFS final rule, while maintaining the current PE/HR data. This results in changes to the work RVU pool, and therefore, yields a different estimated conversion factor.

TABLE D-B23: CY 2025 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY UNDER THREE ALTERNATIVES CONSIDERED FOR CY 2026

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
Estimated Conversion Factor			$32.35			$38.68	$35.26
ALLERGY/IMMUNOLOGY	TOTAL	$218	-1%	-3%	-3%	-3%	-3%
	Non-Facility	$211	-1%	-3%	-3%	-4%	-3%
	Facility	$7	0%	-1%	-2%	6%	4%
ANESTHESIOLOGY	TOTAL	$1,591	2%	5%	8%	7%	3%
	Non-Facility	$315	0%	-1%	-2%	-3%	-3%
	Facility	$1,276	2%	7%	11%	10%	5%
AUDIOLOGIST	TOTAL	$74	0%	0%	13%	0%	2%
	Non-Facility	$72	0%	0%	13%	0%	1%
	Facility	$3	0%	-1%	6%	8%	6%
CARDIAC SURGERY	TOTAL	$166	-1%	3%	-2%	0%	-3%
	Non-Facility	$30	-2%	-2%	4%	-3%	-5%
	Facility	$136	0%	5%	-3%	0%	-3%
CARDIOLOGY	TOTAL	$6,117	0%	0%	7%	1%	-1%
	Non-Facility	$3,826	-1%	-1%	9%	-2%	-3%
	Facility	$2,290	0%	0%	3%	5%	2%
CHIROPRACTIC	TOTAL	$656	1%	1%	-5%	2%	4%
	Non-Facility	$654	1%	1%	-5%	2%	4%
	Facility	$2	1%	1%	2%	9%	7%
CLINICAL PSYCHOLOGIST	TOTAL	$737	3%	3%	5%	12%	8%
	Non-Facility	$595	3%	3%	4%	11%	8%
	Facility	$142	3%	3%	10%	17%	10%
CLINICAL SOCIAL WORKER	TOTAL	$854	4%	4%	6%	13%	10%
	Non-Facility	$722	4%	4%	5%	13%	9%
	Facility	$132	4%	4%	10%	18%	11%
COLON AND RECTAL SURGERY	TOTAL	$151	0%	1%	-7%	-2%	-2%
	Non-Facility	$55	0%	1%	-7%	-4%	-4%
	Facility	$96	0%	1%	-7%	-1%	-2%
CRITICAL CARE	TOTAL	$333	0%	-1%	1%	4%	2%
	Non-Facility	$53	0%	0%	3%	-3%	-1%
	Facility	$281	0%	-1%	0%	5%	2%
DERMATOLOGY	TOTAL	$3,885	0%	-1%	-8%	-3%	-3%
	Non-Facility	$3,740	0%	-1%	-8%	-3%	-3%
	Facility	$144	0%	0%	-7%	3%	3%
DIAGNOSTIC TESTING FACILITY	TOTAL	$942	-2%	-2%	17%	-2%	-8%
	Non-Facility	$940	-2%	-2%	17%	-2%	-8%
	Facility	$1	0%	2%	0%	8%	4%

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
EMERGENCY MEDICINE	TOTAL	$2,440	0%	0%	2%	6%	2%
	Non-Facility	$205	0%	-1%	0%	-4%	-1%
	Facility	$2,235	0%	0%	3%	7%	2%
ENDOCRINOLOGY	TOTAL	$517	0%	1%	0%	-2%	1%
	Non-Facility	$415	1%	1%	0%	-4%	0%
	Facility	$102	0%	0%	-2%	5%	3%
FAMILY PRACTICE	TOTAL	$5,515	0%	0%	0%	-2%	1%
	Non-Facility	$4,424	0%	0%	0%	-4%	0%
	Facility	$1,090	0%	0%	-1%	5%	3%
GASTROENTEROLOGY	TOTAL	$1,453	0%	0%	0%	0%	0%
	Non-Facility	$532	0%	0%	-1%	-4%	-2%
	Facility	$921	0%	0%	0%	2%	1%
GENERAL PRACTICE	TOTAL	$379	0%	0%	0%	-1%	0%
	Non-Facility	$304	0%	0%	1%	-2%	-1%
	Facility	$75	0%	0%	-1%	4%	2%
GENERAL SURGERY	TOTAL	$1,602	0%	0%	-5%	-1%	-2%
	Non-Facility	$464	-1%	-1%	-1%	-3%	-3%
	Facility	$1,138	0%	1%	-6%	-1%	-2%
GERIATRICS	TOTAL	$222	1%	1%	1%	0%	2%
	Non-Facility	$149	1%	2%	2%	-2%	1%
	Facility	$74	0%	0%	-1%	4%	3%
HAND SURGERY	TOTAL	$265	-1%	-2%	-7%	-5%	-4%
	Non-Facility	$141	0%	0%	-2%	-4%	-2%
	Facility	$124	-3%	-4%	-13%	-7%	-6%
HEMATOLOGY/ONCOLOGY	TOTAL	$1,579	-1%	-1%	-1%	-1%	-1%
	Non-Facility	$1,024	-1%	-1%	0%	-4%	-3%
	Facility	$555	0%	0%	-2%	6%	3%
INDEPENDENT LABORATORY	TOTAL	$561	0%	0%	0%	2%	-3%
	Non-Facility	$547	0%	0%	0%	1%	-3%
	Facility	$14	0%	0%	-11%	10%	7%
INFECTIOUS DISEASE	TOTAL	$555	0%	0%	-1%	4%	2%
	Non-Facility	$86	-1%	-1%	-1%	-4%	-3%
	Facility	$469	0%	0%	-1%	5%	3%
INTERNAL MEDICINE	TOTAL	$9,491	0%	0%	0%	1%	1%
	Non-Facility	$4,714	0%	1%	1%	-4%	0%
	Facility	$4,777	0%	0%	-1%	5%	3%
INTERVENTIONAL PAIN MGMT	TOTAL	$839	0%	-2%	-4%	-2%	-2%
	Non-Facility	$660	0%	-2%	-3%	-4%	-3%
	Facility	$179	0%	-2%	-5%	3%	2%
INTERVENTIONAL RADIOLOGY	TOTAL	$445	-2%	-1%	5%	1%	-4%
	Non-Facility	$273	-3%	-4%	7%	-2%	-9%
	Facility	$172	1%	4%	1%	7%	3%
MULTISPECIALTY CLINIC/OTHER PHYS	TOTAL	$152	0%	0%	-2%	1%	1%
	Non-Facility	$76	0%	-1%	-1%	-3%	-1%
	Facility	$76	0%	0%	-2%	5%	3%
NEPHROLOGY	TOTAL	$1,706	0%	4%	0%	2%	2%
	Non-Facility	$1,020	1%	7%	1%	0%	1%
	Facility	$686	0%	1%	-1%	5%	3%
NEUROLOGY	TOTAL	$1,333	0%	-3%	-4%	0%	0%
	Non-Facility	$852	0%	-3%	-5%	-3%	-2%
	Facility	$481	0%	-1%	-4%	5%	3%
NEUROSURGERY	TOTAL	$706	0%	-4%	-11%	-3%	-5%
	Non-Facility	$121	0%	-1%	-2%	-4%	-1%
	Facility	$585	-1%	-5%	-13%	-3%	-6%

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
NUCLEAR MEDICINE	TOTAL	$50	0%	3%	8%	5%	1%
	Non-Facility	$24	-1%	0%	13%	0%	-5%
	Facility	$26	1%	6%	4%	10%	6%
NURSE ANES / ANES ASST	TOTAL	$1,056	1%	7%	11%	9%	3%
	Non-Facility	$21	1%	6%	10%	7%	3%
	Facility	$1,035	1%	7%	11%	9%	4%
NURSE PRACTITIONER	TOTAL	$7,029	0%	0%	-1%	0%	1%
	Non-Facility	$4,611	0%	0%	-1%	-2%	0%
	Facility	$2,418	0%	0%	-1%	4%	3%
OBSTETRICS/GYNECOLOGY	TOTAL	$565	-1%	0%	-1%	-2%	-2%
	Non-Facility	$386	-1%	0%	1%	-3%	-2%
	Facility	$179	0%	0%	-4%	0%	0%
OPHTHALMOLOGY	TOTAL	$4,667	-2%	-1%	2%	-5%	-2%
	Non-Facility	$3,294	-2%	-2%	1%	-6%	-3%
	Facility	$1,372	-1%	-1%	4%	-4%	0%
OPTOMETRY	TOTAL	$1,361	-1%	-1%	1%	-4%	-1%
	Non-Facility	$1,297	-1%	-1%	0%	-4%	-1%
	Facility	$64	0%	0%	3%	-1%	2%
ORAL/MAXILLOFACIAL SURGERY	TOTAL	$64	0%	-1%	15%	-3%	-3%
	Non-Facility	$52	0%	-1%	18%	-3%	-3%
	Facility	$12	0%	-1%	1%	0%	1%
ORTHOPEDIC SURGERY	TOTAL	$3,426	-1%	-2%	-7%	-5%	-3%
	Non-Facility	$1,498	0%	0%	-1%	-4%	-2%
	Facility	$1,928	-2%	-3%	-11%	-6%	-5%
OTHER	TOTAL	$58	-1%	-1%	-3%	-2%	-1%
	Non-Facility	$47	-1%	-2%	-3%	-4%	-2%
	Facility	$12	1%	0%	-3%	5%	3%
OTOLARNGOLOGY	TOTAL	$1,155	0%	-1%	-7%	-3%	-2%
	Non-Facility	$918	0%	-1%	-6%	-4%	-3%
	Facility	$237	0%	-1%	-9%	0%	0%
PATHOLOGY	TOTAL	$1,187	0%	0%	-8%	6%	2%
	Non-Facility	$629	0%	0%	-3%	3%	-2%
	Facility	$558	0%	1%	-13%	9%	6%
PEDIATRICS	TOTAL	$55	0%	0%	0%	0%	1%
	Non-Facility	$35	0%	0%	0%	-3%	-1%
	Facility	$20	1%	0%	-1%	6%	3%
PHYSICAL MEDICINE	TOTAL	$1,127	0%	-1%	-3%	0%	0%
	Non-Facility	$550	0%	-2%	-4%	-3%	-2%
	Facility	$576	0%	-1%	-2%	4%	3%
PHYSICAL/OCCUPATIONAL THERAPY	TOTAL	$5,905	0%	0%	-1%	-3%	2%
	Non-Facility	$5,905	0%	0%	-1%	-3%	2%
	Facility	$	4%	2%	-2%	11%	9%
PHYSICIAN ASSISTANT	TOTAL	$3,699	0%	0%	-3%	-1%	0%
	Non-Facility	$2,531	0%	0%	-3%	-3%	-1%
	Facility	$1,169	0%	0%	-3%	3%	1%
PLASTIC SURGERY	TOTAL	$303	-1%	-3%	-8%	-4%	-3%
	Non-Facility	$135	-1%	-2%	-8%	-4%	-3%
	Facility	$168	-1%	-3%	-9%	-4%	-2%
PODIATRY	TOTAL	$1,928	0%	0%	-1%	-3%	-2%
	Non-Facility	$1,714	0%	0%	-1%	-4%	-2%
	Facility	$214	0%	0%	-2%	0%	1%
PORTABLE X-RAY SUPPLIER	TOTAL	$79	1%	2%	11%	0%	-4%
	Non-Facility	$76	1%	2%	11%	-1%	-4%
	Facility	$3	1%	4%	4%	7%	4%

(A) Specialty	(B) Total: Non-Facility / Facility	(C) Allowed Charges (mil)	(D) Combined Impact CY 2025 Baseline (same as shown in Table 111)	(E) Combined Impact: Current PE/HR; New Specialty Groupings	(F) Combined Impact: Updated PPI/CPI PE/HR Data; Current 2006-based MEI Cost Shares	(G) Combined Impact: Current PE/HR; Updated AMA Cost Shares	(H) Combined Impact: Current PE/HR; Updated Cost Shares Derived by CMS
PSYCHIATRY	TOTAL	$867	1%	1%	0%	3%	3%
	Non-Facility	$508	1%	1%	0%	0%	2%
	Facility	$359	0%	0%	-1%	7%	4%
PULMONARY DISEASE	TOTAL	$1,269	0%	0%	1%	2%	1%
	Non-Facility	$550	0%	0%	4%	-3%	-1%
	Facility	$719	0%	-1%	0%	6%	3%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	TOTAL	$1,538	0%	-12%	-6%	2%	-2%
	Non-Facility	$1,048	-1%	-12%	-1%	-1%	-6%
	Facility	$490	2%	-13%	-16%	9%	6%
RADIOLOGY	TOTAL	$4,557	0%	3%	4%	6%	2%
	Non-Facility	$2,004	-1%	0%	8%	2%	-3%
	Facility	$2,553	1%	5%	1%	10%	6%
RHEUMATOLOGY	TOTAL	$520	0%	0%	-1%	-3%	-2%
	Non-Facility	$467	-1%	0%	0%	-4%	-2%
	Facility	$53	0%	0%	-2%	6%	3%
THORACIC SURGERY	TOTAL	$297	-1%	3%	-2%	-1%	-4%
	Non-Facility	$59	-2%	-2%	3%	-3%	-5%
	Facility	$238	0%	4%	-3%	0%	-3%
UROLOGY	TOTAL	$1,617	0%	2%	1%	-1%	-1%
	Non-Facility	$1,136	0%	2%	1%	-3%	-2%
	Facility	$480	0%	3%	0%	4%	2%
VASCULAR SURGERY	TOTAL	$998	-2%	-2%	5%	-1%	-6%
	Non-Facility	$715	-3%	-3%	6%	-3%	-8%
	Facility	$283	0%	1%	0%	3%	-1%
TOTAL	TOTAL	$90,861	0%	0%	0%	0%	0%
	Non-Facility	$57,431	0%	0%	0%	-2%	-1%
	Facility	$33,429	0%	0%	-1%	4%	2%

As stated previously, the AMA's new specialty groupings in the updated PPI and CPI Surveys result in consequential redistributions shown in Column E, with estimated specialty-level impacts ranging from -13 percent (facility-based Radiation Oncology and Radiation Therapy Centers) to +7 percent (Nurse Anesthetist, and non-facility Nephrology).

Relative to the CY 25 PFS final rule baseline, adopting the PE/HR data from the new PPI and CPI Surveys would result in large specialty-level impacts shown in Column F. New data such as these would typically be phased in over multiple years to reduce year-on-year changes. After fully phasing in the changes, adopting the new PPI/CPI data would result in specialty-level impacts with negative impacts as low as -16 percent for facility-based

Radiation Oncology and Radiation Therapy Centers and increases as large as +18% non-facility Oral/Maxillofacial Surgery. Of note, the AMA did not provide updated PE/HR data for the IDTF specialty, so this scenario retains the current PE/HR values for that specialty.

In addition to updated PE/HR data for PFS ratesetting, the information from the PPI and CPI Surveys could be used to develop new cost share weights to adjust the aggregate pools of PE RVUs and the relativity adjustment to reflect more recent data, to reach the proportions of work, PE, and MP reported in the new surveys. The AMA has reported work, PE, and MP shares of 60.8 percent, 37.0 percent, and 2.3 percent, respectively, in the new PPI Survey data.[485] As discussed in detail in section II.B. of this final rule, we have numerous concerns with the cost shares as reported by the AMA in the PPI Survey data. It is our understanding that these PPI Survey cost shares ignore non-physician specialties that were surveyed in the CPI Survey, even though those specialties are included in PFS ratesetting, and therefore derive payment from the same pools of work, PE, and MP as the physician specialties included in the PPI Survey. Additionally, it seems that the AMA calculated specialty-level shares and averaged these shares across specialties, which is mathematically different than estimating the share of total work, PE, and MP across all specialties. (That is, the average of shares does not need to equal shares of the total.) This represents a change from how the cost shares are currently calculated by the MEI and we believe this methodology runs counter to the goal of adjusting the aggregate pools of PE RVUs and the relativity adjustment to reach the proportions of work, PE, and MP. Despite our concerns, we are displaying the specialty-level impacts of incorporating these new cost shares, as directly reported by the AMA, in column G, which would result in specialty impacts ranging from -7 percent (facility-setting Hand Surgery) to +18 percent (for facility-setting Clinical Social Worker).

Due to our concerns with the AMA's methodology for reporting cost shares, we developed cost shares that account for both the PPI and CPI Survey data into an estimate of total shares across physician and non-physician specialties using weights from Medicare volumes. Using either PFS RVUs or physician time file time-weighted shares yields similar results, with an estimated 54.4 percent or 54.8 percent work share, respectively. To do this, we multiplied the specialty-level estimates of work, PE, and MP by, for example, total PFS RVUs for the specialty grouping, added these amounts across specialty

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[485] https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.

groupings, and calculated the shares of these sums. As a result, we calculate cost shares of total work, PE, and MP to be 54.4 percent, 43.8 percent, and 1.7 percent, respectively, when using PFS RVUs to weight the specialty-level values reported in the PPI and CPI Surveys. We displayed the specialty-level impacts of using these cost shares derived by through this methodology, while retaining current PE/HR values results, in Column H, which range from -9 percent to 11 percent (for non-facility Interventional Radiology and facility-setting Clinical Social Worker specialties, respectively).

Because of the significant redistributive effects of all the alternatives considered, as well as the concerns with the underlying PPI and CPI Survey data, we proposed to delay these adjustments to allow public comments on the PPI and CPI Surveys discussed in section II.B. of this final rule, and to maintain use of the current 2006-based MEI cost share weights. Because there are significant concerns with the PPI and CPI Survey data, outlined in detail in section II.B. of this final rule, and significant time has elapsed since the last recalibration of the cost share weights, we believe it is important to allow public comment on the use of the PPI and CPI Survey data, as well as the updated 2017-based MEI, discussed in detail in the CY 2023 PFS final rule, before we incorporate any updated cost shares into PFS ratesetting. Of note, the 2017-based MEI cost shares, the PPI Survey cost shares as reported by the AMA, and the cost shares derived by CMS from the PPI and CPI Survey data result in drastically different PE shares, and the current 2006-based MEI cost shares fall in the middle of the them, therefore, we continued to believe that proposing to delay the implementation of any alternative cost share weights is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Similarly, we proposed to delay the implementation of any updated cost share weights for use in the practice expense (PE) Geographic Practice Cost Index (GPCI) for CY 2026 to solicited public comment on all considerations before we incorporate any updated cost share weights into the PE GPCIs. We refer readers to the section below, and section II.N. of this final rule for more discussion on alternatives considered regarding this proposal.

3. Alternatives Considered for the Practice Expense (PE) Geographic Practice Cost Index (GPCI)

As discussed in section II.N. of this final rule, we use the MEI cost share weights to weight the four components of the PE GPCI: employee wages, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses. As the MEI cost shares are updated, we have

historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI. Due to the concurrent GPCI update and rebasing and revision of the MEI for CY 2023, we proposed to maintain the use of the current 2006-based MEI cost share weights for the CY 2023 GPCIs instead of the updated 2017-based MEI, to allow interested parties the opportunity to review and comment on the rebased and revised MEI cost share weights. Similarly, we proposed to delay the implementation of any updated cost share weights for the CY 2026 GPCIs due to the consideration of the AMA's PPI and CPI Survey data.

Additionally, we received data from the AMA's PPI and CPI Surveys, however, these data lack the specific breakdown of practice expense that we would need to consider its use to weight the four components of the PE GPCI for CY 2026, including Office Rent and Purchased Services, which are not explicitly described in the PPI and CPI Survey data. Because the Survey data lacks constituent components of the PE GPCI, we considered possible derivations of weights from the PPI and CPI Survey for use in the PE GPCI for consideration in possible future rulemaking. Because the derivation of these weights required mapping and methodology proposals discussed below, we did not consider their use in the CY 2026 PE GPCI update and did not develop CY 2026 PE GPCIs based on these weights for display purposes but are displaying the derived weights for possible consideration in future rulemaking. We did not believe it would be beneficial to display the resulting CY 2026 PE GPCIs from these derived weights because the PE GPCI values would inevitably look different if/when we proposed to update the weights due to the underlying updated data.

For the derived weights, we started with a possible mapping of the PPI and CPI Survey direct (labor, supplies and equipment) and indirect PE (administrative, overhead, information technology and other) data to the four components of the PE GPCI based, as shown below in Table D-B24.

TABLE D-B24: PROPOSE MAPPING FOR PPI AND CPI SURVEY DATA CATEGORIES TO THE PE GPCI COMPONENTS

	PE GPCI Component			
	Employee Wages	**Purchased Services**	**Office Rent**	**Supplies and Equipment**
Clinical Labor	100%	0%	0%	0%
Supplies	0%	0%	0%	100%
Equipment	0%	0%	0%	100%
Administrative	0%	50%	50%	0%
Overhead	0%	50%	50%	0%
Information Technology	0%	100%	0%	0%
Other	0%	50%	50%	0%

Secondly, we combined the PPI and CPI Survey data and weighted the data by RVUs to develop a combined PPI and CPI Survey "All" line, analogous to the AMA's PPI Survey results "All" line[486], which was not provided for the CPI Survey data[487]. We then used the calculated direct and indirect totals from the PPI and CPI Survey data (weighted them by total RVUs) for each PE GPCI element based on the proposed mapping for the 4 PE GPCI components above to derive new weights for each of the 4 PE GPCI components, as shown below in Table D-B25.

TABLE D-B25: ALTERNATIVE DERIVED WEIGHTS FROM THE PPI AND CPI SURVEY DATA

		Weights of the Four PE GPCI Components		
Proposed Map to PE Shares*	**Calculated Direct/Indirect Total**	**New Weights Derived from PPI and CPI Surveys**	**Current Weights under the 2006-based MEI**	**Weights under the 2017-based MEI**
Employee Wages	38.78	25.476%	36.917%	49.776%
Purchased Services	53.76	35.317%	18.053%	26.245%
Office Rent	46.35	30.449%	22.799%	11.117%
Supplies & Equipment**	13.34	8.764%	22.231%	12.862%
Total	152.22	100%	100%	100%

*weighted by total RVUs
**CMS assumes a national market for such items and therefore assigns a value of 1.00 for this component in each PFS locality, therefore, a decrease in its share of the PE GPCI would possibly lead to more variation in the resulting PE GPCI across payment areas.

We solicited comments on the weights displayed in Table D-B25, and any alternative methodologies to weight and or map the PPI and CPI Survey data to derive weights used to weight the four components of the PE GPCI for possible consideration in future rulemaking. Because any alternative derivation or weighting methodology for the PPI and CPI Survey data will result in different shares than displayed above, we do not believe that displaying the resulting CY 2026 PE GPCI based on these shares

[486] https://www.ama-assn.org/system/files/table-1-results-from-ppi.pdf.
[487] https://www.ama-assn.org/system/files/table-1-results-from-cpi-final.pdf.

would be beneficial until we provide opportunity for the public to comment on this methodology. Additionally, because CY 2026 is a GPCI update, there would be a confounding effect of these updated shares due to the implementation of updated data required for a triennial GPCI update.

4. Alternatives Considered for Changes Related to Medicare Part B Payment for Skin Substitutes When Used During a Covered Application Procedure in the Non-facility Setting

As discussed in detail in section II.K.D. of this final rule, starting January 1, 2026, we proposed to pay for the provision of certain groups of skin substitute products used during a covered application procedure (CPT codes 15271 through 15278) as supplies. These skin substitutes will be paid as incident-to supplies under the PFS in the non-facility setting in accordance with section 1861(s)(2)(A) of the Act. While costs associated with supplies are usually bundled into the PE RVUs for particular services in non-facility settings, these products have been paid separately for many years in the non-facility setting, where the majority of these products are currently used.

CMS considered several alternative approaches to calculate changes in spending. Each alternative relies on the same underlying data on skin substitute product volume—2024 volume measured in billing units for skin product HCPCS codes included in analysis as described above. The alternatives and corresponding spending change estimates vary in terms of the rate(s) applied to this fixed volume. Each alternative results in a corresponding saving estimate relative to the status quo spending at 2024 volumes and payment rates of $10.3B.

All alternatives considered by CMS share some common features. Quarterly 2024 rates start with the ASP for skin substitute product HCPCS codes included in the October 2024 ASP pricing file or, for other codes, the OPPS geometric mean cost for the HCPCS code prior to OPPS packaging rules or, for all other codes, the average payment per billing unit in calendar year 2024 professional claims. These values were then applied to volume shares calculated in different ways to calculate annual rates.

We estimate that under this proposal, which assumes a single rate of approximately $125.38, there would be an estimated savings of $9.4 billion. The first alternative, which assumes a single rate of $65.85 calculated using outpatient facility volume shares, yields savings of $9.79 billion, or a 95 percent reduction from the status quo. Finally, another approach applies the PMA-based rate ($259.47) and another rate, $125.38, calculated using data from HCT/P products and outpatient facility volume shares

only, to HCT/P and 510(k) products. Savings under this approach were $9.29 billion, a 90 percent reduction in spending relative to the status quo.

5. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. In section IV.A.4.g.(2).(c). of this final rule, we proposed to set the performance threshold to 75 points for the CY 2026 MIPS performance period/ CY 2028 MIPS payment year through CY 2028 MIPS performance period/ CY 2030 MIPS payment. We refer readers to section IV.B.2.b.(2). of this final rule for discussion of this policy and alternatives considered.

6. Alternatives Considered Related to the Ambulatory Specialty Model

In section III.D of this final rule, we discussed the proposed mandatory ASM. As proposed, we would test whether ASM leads to improved chronic condition management, higher quality care, and reduced costs by incentivizing ASM participants with the opportunity for positive payments adjustments to Medicare Part B covered professional services payments based on their performance on data reported on quality, cost, improvement activities, and CEHRT interoperability.

Throughout this final rule, we have identified our proposed policies and alternatives that we have considered and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. This final rule provides descriptions of the requirements that we would mandate, identifies the payment methodology to be tested, and presents rationales for our decisions and, where relevant, alternatives that we considered. For example, we considered defining an ASM participant as a subgroup within a TIN comprised of NPIs that individually meet the proposed ASM participant eligibility criteria for a given ASM performance year and will report the required measures and activities as a subgroup within the TIN. Another example is that we considered an alternative scoring approach where each of the four proposed ASM performance categories would be weighted to produce a final score, instead of the proposed negative scoring adjustments to the final score computed from quality and cost ASM performance category scores based on performance within the improvement activities and Promoting Interoperability ASM performance categories.

We noted that the impact estimates summarized in this section of this final rule are based on the proposed policies identified throughout the rule.

We solicited comments on our proposals and on the alternatives that we have identified in this rule.

H. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in the CY 2025 PFS final rule (89 FR 98551), the health equity benchmark adjustment finalized in that rule (in this rule being renamed the "population adjustment") will mainly provide upwards adjustments to benchmarks for – and likely draw increased participation from – new ACOs with particular focus on coordinating care for beneficiaries in underserved communities. New ACOs of this type are therefore projected to ultimately increase assignment to Shared Savings Program ACOs by roughly 500,000 beneficiaries per year, ranging from 50,000 to 1.0 million at the low and high ends of this projection range. Beyond retaining this impact via the "population adjustment," the renaming of the benchmark adjustment being finalized in this rule is not expected to have a material net impact on overall program participation or the number of beneficiaries receiving care management from ACOs.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in MIPS (as shown in Table D-B26). In performance year 2024, ACOs scored better than comparable MIPS groups[488] on all three eCQMs in the APP quality measure set, and the difference was statistically significant for Quality ID: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan ($p < .001$) and Quality ID: 236 Controlling High Blood Pressure ($p < .01$). ACOs also performed better than comparable MIPS groups on two of the three MIPS CQMs in the APP quality measure set and the difference was statistically significant for Quality ID: 236 Controlling High Blood Pressure ($p < .01$). Additionally, ACOs performed better than comparable MIPS groups on five of the ten patients experience survey measures that contribute to Quality ID: 321 Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS, and for one of these

[488] Quality Payment Program measurement data are for MIPS groups that have 16 or more clinicians. The mean number of beneficiaries for MIPS groups with 16 or more clinicians is 10,741.

summary survey measures the difference was statistically significant: CAHPS-1 Getting Timely Care, Appointments ($p < .01$).

We note there are key differences between the Shared Savings Program and MIPS that limit our analysis of ACOs' performance on the eCQMs/MIPS CQMs and the CAHPS for MIPS Summary Survey Measures compared to MIPS groups. Specifically, Shared Savings Program ACOs are required to report the eCQMs/MIPS CQMs included in the APP quality measure set; whereas MIPS groups can choose which eCQMs and MIPS CQMs they report on and tend to choose those they will perform well on. Shared Savings Program ACOs are required to administer the CAHPS for MIPS Survey, while it is optional for MIPS groups. A large number of MIPS groups do not administer the CAHPS for MIPS Survey as they are less likely to meet the minimum sample size required to administer the survey, coupled with the tendency of MIPS groups to choose measures they will perform well on.

TABLE D-B26: PY 2024 QUALITY MEASURES THAT SHARED SAVINGS PROGRAM ACOs PERFORMED BETTER ON THAN COMPARABLE MIPS GROUPS

Quality #	Measure Title	Difference in Mean ACO and MIPS Group Performance Rates for PY 2024 (%)[1]
	eCQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-3.75[2]
134	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	9.11[4]
236	Controlling High Blood Pressure	3.39[3]
	MIPS CQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-7.63[2]
236	Controlling High Blood Pressure	8.59[3]
321	**CAHPS for MIPS**	0.08
CAHPS-1	Getting Timely Care, Appointments, and Information	2.47[3]
CAHPS-5	Health Promotion and Education	0.84
CAHPS-6	Shared Decision Making	0.08
CAHPS-7	Health Status and Functional Status	0.11
CAHPS-11	Stewardship of Patient Resources	0.17
	Administrative Claims	
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	-0.59[2]

Notes:
[1]The numbers in this column represent the mean ACO performance rate minus the mean MIPS group performance rate for each measure.
[2] This is an inverse measure, and lower number indicates better quality performance.
[3] Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.01$).
[4] Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.001$)

Additionally, ACOs showed improvement for 7 of the 10 CMS Web Interface measures and statistically significant improvement for 2 out of the 10 measures, in performance year 2024 relative to performance year 2023 (as shown in Table D-B27).

TABLE D-B27: CMS WEB INTERFACE MEASURES WITH IMPROVEMENT AMONG SHARED SAVINGS PROGRAM ACOS BETWEEN PY 2023 AND PY 2024

Quality #	Measure Title	Difference in Mean ACO Performance Rates between PY 2023 and PY 2024 (%)[1]
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-0.4[2,3]
112	Breast Cancer Screening	0.57
113	Colorectal Cancer Screening	0.67
134	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	0.49
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0.69
236	Controlling High Blood Pressure	1.69[4]
370	Depression Remission at Twelve Months	0.77

Notes:
[1]The numbers in this column represent the mean ACO performance rate in PY 2024 minus the mean ACO performance rate in PY 2023 for each measure.
[2] This is an inverse measure, and lower number indicates better quality performance.
[3] Indicates statistically significant differences between ACOs' mean performance rates between PY 2023 and PY 2024 ($p < 0.01$).
[4] Indicates statistically significant differences between ACOs' mean performance rates between PY 2023 and PY 2024 ($p < 0.001$).

Based on ACOs' quality performance results historically (as shown in Tables D-B26 and D-B27), we anticipate that the policies finalized in this final rule will enable ACOs to continue to improve the quality of care for the beneficiaries they serve.

Increased participation in the Shared Savings Program would extend ACO care coordination to additional beneficiaries which can help improve the quality of care they receive.

2. Quality Payment Program

There are several changes in this final rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipated the policies in this final rule will improve the quality and value of care provided to Medicare beneficiaries.

For example, several of the new quality measures include patient-reported outcome-based measures, which could be used to help patients make more informed decisions about treatment options.

Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and could also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which will not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

3. Ambulatory Specialty Model

We anticipated that ASM will have no impact on cost to beneficiaries. Like MIPS, ASM payment adjustments would not affect Medicare beneficiary coinsurance amounts. The coinsurance will be calculated based on the Medicare allowed amounts before any ASM payment adjustment multipliers are applied to Medicare Part B payments for covered professional services.

I. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rulemaking, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this rule will be the number of reviewers of this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rulemaking. It is possible that not all commenters will review this rule in detail, and it is also possible that some reviewers will choose not to comment on this rule. For these reasons, we believe that the number of commenters will be a fair estimate of the number of reviewers of this year's rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rulemaking is $113.42, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this final rule. For each facility that reviews the rule, the estimated cost is $907.36 (8.0 hours × $113.42). Therefore, we estimated that the total cost of reviewing this regulation is $12,239,821 ($907.36 × 13,549 reviewers on this year's proposed rule).

J. Accounting Statement

As required by OMB Circular A-4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), in Tables 113 through 115 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2025 to CY 2026 based on the FY 2026 President's Budget baseline.

TABLE D-B28: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

CATEGORY	TRANSFERS
CY 2026 Annualized Monetized Transfers	Estimated increase in expenditures of $0.4 billion for PFS CF update.
Bearers of Transfer Gain	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE D-B29: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

CATEGORY	TRANSFER
CY 2026 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion
Bearers of Transfer Gain	Beneficiaries to Federal Government.

TABLE D-B30: ACCOUNTING STATEMENT FOR PROVISIONS FOR MEDICARE SHARED SAVINGS PROGRAM (CYS 2026 to 2035) ($ MILLIONS)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized: Discount rate: 3%	-$2.2 million	-$70.1 million	$72.9 million	Tables D-B11 and D-B12; summarized in total in Table D-B13
Annualized monetized: Discount rate: 7%	-$2.5 million	-$66.2 million	$67.5 million	Tables D-B11 and D-B12; summarized in total in Table D-B13

Notes: Negative values reflect a reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

K. Conclusion

The analysis in the previous sections, together with the remainder of this final rule, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this rule, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VII. Waiver of 60-Day Delay in the Effective Date

In the absence of an appropriation for CY 2026 or a Continuing Resolution, there was a lapse in funding, which began on October 1, 2025, and is ongoing at the time of drafting this final rule. During that time, only excepted operations have continued. Accordingly, most of the work on this final rule was not completed in accordance with our usual schedule for final CY payment rules, which aims for an issuance date of November 1 followed by an effective date of January 1 to ensure that the policies are effective at the start of the calendar year to which they apply.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. We believe it would be contrary to the public interest to delay the effective date of the MPFS portions of this final rule. In accordance with section 1848(b)(1) of the statute, the MPFS is a calendar-year payment system. We typically issue the final rule by November 1 of each year to comply with section 1848(b)(1) of the statute and to ensure that the payment policies for the system are effective on January 1, the first day of the calendar year to which the policies are intended to apply. If the effective date of this final rule is delayed by 60 days, the MPFS for CY 2026 adopted in this final rule will not be effective at of the beginning of the payment year. In this final rule, we review and revise values for specific services, and adopt or revise other policies that relate to the MPFS for CY 2026 or future years. Section 1848(c)(2)(B)(ii)(II) of the Act requires that adjustments to relative values under the MPFS be made in a budget neutral manner. We believe that, in order to preserve budget neutrality as required by statute and to promote an orderly transition to a new payment year, it is in the public interest for all of these MPFS policies to take effect in conjunction with the statutory update to the CF for CY 2026, and we find that it would be contrary to the public interest to do otherwise. We are finalizing the MPFS in this CY 2026 final rule and, in order to adhere to the statutory requirements that an adjusted CF apply to services furnished on or after January 1, 2026, and that budget neutrality be maintained, this final rule must be effective on that date.

Therefore, we find good cause to waive the 60-day delay in the effective date for this final rule as explained above. We note that our waiver of the delayed effective date only applies to the provisions noted above that are being adopted in this final rule.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 31, 2025.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405-FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.2401(b) is amended by adding the definition of "Direct Supervision" in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

* * * * *

Direct supervision means that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

3. Section 405.2463 is amended by revising paragraph (b)(3) to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(b) * * *

(3) *Visit-Mental health*. A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder. On or after October 1, 2025, in the case of mental health visits furnished via interactive, real-time, audio and video

telecommunications technology or audio-only interactions, within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

4. Section 405.2464 is amended by—

a. Revising paragraph (c)(2);

b. Adding paragraph (c)(8); and

c. Revising paragraph (e);

The revisions and addition read as follows:

§ 405.2464 Payment rate.

* * * * *

(c) * * *

* * * * *

(2) For psychiatric collaborative care model (CoCM) services furnished between January 1, 2018, and December 31, 2025, payment is based on the average of the national non-facility PFS payment rate set for each psychiatric CoCM service and updated annually based on the PFS amounts.

* * * * *

(8) For CoCM services furnished on or after January 1, 2026, payment is based on the PFS national non-facility payment rate.

* * * * *

(e) *Payment for communication technology-based and remote evaluation services*.

(1) For communication technology-based and remote evaluation services furnished between January 1, 2019, and December 31, 2025, payment to RHCs and FQHCs is at the rate set for each of the

RHC and FQHC payment codes for communication technology-based and remote evaluation services.

(2) For communication technology-based services furnished on or after January 1, 2026, payment to RHCs and FQHCs is based on the PFS national non-facility payment rate.

(3) For remote evaluation services furnished on or after January 1, 2026, payment to RHCs and FQHCs is based on the PFS national non-facility payment rate.

* * * * *

§ 405.2469 [Amended]

6. Section 405.2469 is amended in paragraph (d) by removing the phrase "Additionally, beginning January 1, 2025,"" and adding in its place the phrase "On or after October 1, 2025,".

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

7. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

8. Section 410.15 is amended by revising paragraph (a), the definition for "First annual wellness visit providing personalized prevention plan services" and "Subsequent annual wellness visit providing personalized prevention plan services" to read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

* * * * *

First annual wellness visit providing personalized prevention plan services * * *

(xiii) At the discretion of the health professional and beneficiary, furnish a Physical Activity and Nutrition Risk Assessment that is standardized and evidence-based.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(xi) At the discretion of the health professional and beneficiary, furnish a Physical Activity and Nutrition Risk Assessment that is standardized and evidence-based.

* * * * *

9. Section 410.26 is amended by revising paragraphs (a)(2) and (c)(2) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(2) *Direct supervision* means, except as provided in paragraphs (a)(2)(i) and (ii) of this section, the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii). The presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

* * * * *

(c) * * *

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in §§ 410.59(a)(3)(iii), 410.60(a)(3)(iii), and 410.62(a)(3)(iii).

10. Section 410.32 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(3) * * *

(ii) Direct supervision in the office setting means that the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. The presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

* * * * *

11. Section 410.62 is amended by revising paragraph (a) to read as follows:

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule*. Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets

the qualifications for a speech-language pathologist in § 484.115 of this chapter and only under the following conditions:

* * * * *

12. Section 410.79 is amended--

a. In paragraph (b) by--

i. Revising the definitions of "Extended flexibilities period" and "Online;"

ii. Adding the definitions of "Live Coach interaction," "Online delivery period" and "Online session;" in alphabetical order.

b. Revising paragraphs (c)(1)(ii) and (e)(3)(iii)(C); and

c. Adding paragraph (f).

The revisions and additions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Extended flexibilities period refers to the 6-year period (January 1, 2024 to December 31, 2029) for the Extended flexibilities to apply.

* * * * *

Live Coach interaction refers to the bi-directional communication between the Coach and beneficiary.

* * * * *

Online means sessions that are delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach teaching the content.

Online delivery period refers to the 4-year period (January 1, 2026 to December 31, 2029) to test an asynchronous delivery modality of the Set of MDPP services. During this time, MDPP suppliers may deliver the Set of MDPP services through the Online modality.

Online session refers to an MDPP session that is not furnished in person or via distance learning and that is furnished in a manner consistent with the DPRP standards for Online sessions.

* * * * *

(c) * * *

(1) * * *

(ii) Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session or reflected in the beneficiary's medical record dated within 5 calendar days of the MDPP session.

(e) * * *

(3) * * *

(iii) * * *

(C) Self-reported weight measurements from the digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous Online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the digital scale, or the MDPP supplier receives two date-stamped photos or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. If choosing to submit two photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home or other reasonable location outside of an in-person delivery site, and both photos must be date-stamped.

* * * * *

(d) * * *

(1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use In-person, Distance learning, or Online delivery. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each session must be furnished in accordance with the following requirements:

(i) * * *

(ii) * * *

(iii) * * *

* * * * *

(f) *MDPP Online delivery.*

(1) Notwithstanding paragraphs (a) through (e) of this section, the policies described in this paragraph (f) apply during the Online delivery period.

(2) During the Online delivery period, MDPP suppliers are not required to maintain in-person delivery capabilities of the Set of MDPP services, as applicable during the Online delivery period.

(i) Online sessions must be furnished in a manner consistent with the DPRP Standards regarding program format, Coach interaction, and program intensity and duration to qualify for payment. Online sessions must be delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI) Coach teaching the content.

(A) Live Coach interaction must be offered to each participant during weeks when the beneficiary has engaged with content. E-mails and text messages can count toward the requirements for Live Coach interaction if there is bi-directional communication (that is, organizations may not simply send out an announcement via text or e-mail and count that as live Coach interaction; the beneficiary must have the ability to respond to and get support from the live Coach) between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction. Coaches are required to track participant engagement and completion of online modules. Proactive outreach must be used to encourage Online session completion and beneficiary weight reporting.

(*1*) MDPP suppliers may not require that beneficiaries initiate interactions with the Coach and MDPP suppliers may not use AI or Machine Learning (ML) to replace Live Coach interaction.

(*2*) [Reserved]

(B) Beneficiaries must submit weight measurements on the date in which the Online session is completed. MDPP suppliers must ensure safeguards are in place to ensure the accuracy of beneficiary weight measurements.

(C) For MDPP beneficiaries, MDPP suppliers may not bill for Online Sessions as well as In-Person or Virtual Sessions during the Online delivery period. The Set of MDPP services must be delivered to individual beneficiaries as Online sessions or fully synchronously (that is, In-person,

Distance learning, or In-person with a distance learning component), inclusive of make-up sessions.

(D) MDPP suppliers must ensure that MDPP beneficiaries engage with and understand the content of each Online session. MDPP suppliers may use one or more of the following to ensure engagement and understanding: videos/presentations, email, video conferencing; knowledge checks (multiple choice or short answer); participant contributions to group discussions on a community board; or beneficiary responses to the Coach via email, text message, or in-app messaging.

(ii) [Reserved]

* * * * *

PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

13. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

14. Section 414.84 is amended by—

a. Revising paragraphs (b)(1) introductory text and (b)(2) introductory text;

b. Redesignating paragraphs (c)(3) and (c)(4) as paragraphs (c)(4) and (c)(5);

c. Adding new paragraph (c)(3); and

d. Revising newly redesignated paragraph (c)(4)(ii).

The revisions and addition read as follows:

§ 414.84 Payment for MDPP services.

* * * * *

(b) * * *

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss*. CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in accordance with § 410.79(c)(ii) or described in § 410.79(e)(3)(iii) during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(2) *Performance Goal 2: Achieves 9-percent weight loss*. CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in

accordance with § 410.79(c)(ii) or described in § 410.79(e)(3)(iii) during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(c) * * *

(3) For the duration of Online delivery described in § 410.79(f), the Online HCPCS G-code applies for any Set of MDPP services that are delivered Online, as described in § 410.79(b).

(4) Medicare pays for up to 22 sessions in a 12-month period. The amount of this payment is determined as follows:

(i) * * *

(ii) For a core session or core maintenance session furnished January 1, 2026 through December 31, 2026, $18.

(5) Current Procedural Terminology (CPT) Modifier 76 (repeat services by same physician) must be appended to any claim for G9886, G9887, or G9871 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.

* * * * *

§ 414.610 Basis of payment.

15. Section 414.610 is amended by—

a. Revising paragraph (c)(1)(ii) introductory text; and

b. In paragraph (c)(5)(ii) removing the date "December 31, 2024" and adding in its place the date "September 30, 2025".

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through September 30, 2025, ambulance services originating in.

* * * * *

16. Section 414.802 is amended by—

a. Adding a definition of biological in alphabetical order;

b. Adding the definition of bundled arrangement in alphabetical order; and

These additions and revision read as follows:

§ 414.802 Definitions.

* * * * *

Biological means a product licensed under section 351 of the Public Health Service Act.

Bundled arrangement means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs or biologicals been purchased separately or outside the bundled arrangement.

* * * * *

17. Section 414.804 is amended by—

a. Adding paragraphs (a)(2)(iii) and (iv); and

b. Revising paragraph (a)(5).

The additions and revision read as follows:

§ 414.804 Basis of payment.

(a) * * *

(2) * * *

* * * * *

(iii) The discounts in a bundled arrangement as defined at § 414.802, including those discounts resulting from a contingent arrangement, are allocated proportionately to the dollar value of the units of all drugs or products sold under the bundled arrangement.

(iv) For bundled arrangements where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

* * * * *

(5) *Submission requirements.* Manufacturers must submit the following to CMS within 30 days of the close of the quarter: The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(i) The manufacturer's average sales price, which must be calculated by the manufacturer every calendar quarter. The first quarter submission must be submitted by April 30, 2004.

(ii) Effective January 1, 2026, reasonable assumptions for calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices including documentation of the methodology used to determine fair market value.

(iii) Effective January 1, 2026, certification letter from the recipient of a bona fide service fee as evidence that the fee is not passed on in whole or in part to a client or customer of the recipient of the fee, whether or not the entity takes title to the drug.

* * * * *

18. Section 414.902 is amended by adding the definition of "biological" in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Biological means a product licensed under section 351 of the Public Health Service Act.

* * * * *

19. Section 414.1305 is amended by—

a. Revising paragraph (6) of the definition for "Attribution-eligible beneficiary";

b. Adding the definitions "Covered professional service attribution-eligible beneficiary" and "E/M attribution-eligible beneficiary".

c. In the definition of "high priority measure", the phrase "care coordination, opioid, or health equity-related quality measure." is removed and added in its place is the phrase "care coordination or opioid-related quality measure.";

d. Revising the definitions of “Multispecialty group”, “MVP participant”, and “Single specialty group.

The revisions read as follows:

§ 414.1305 Definitions.

Attribution-eligible beneficiary means a beneficiary who, through the 2025 QP Performance Period:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan;

(2) Does not have Medicare as a secondary payer;

(3) Is enrolled in both Medicare Parts A and B;

(4) Is at least 18 years of age;

(5) Is a United States resident; and

(6) Has a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on evaluation and management services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of evaluation and management and other services.

* * * * *

Covered professional service attribution-eligible beneficiary means a beneficiary who, starting with the 2026 QP Performance Period:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan;

(2) Does not have Medicare as a secondary payer;

(3) Is enrolled in both Medicare Parts A and B;

(4) Is at least 18 years of age;

(5) Is a United States resident; and

(6) Has a minimum of one claim for a Covered Professional Service furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period.

* * * * *

E/M attribution-eligible beneficiary means a beneficiary who, starting with the 2026 QP Performance Period:

(1) Is not enrolled in Medicare Advantage or a Medicare cost plan;

(2) Does not have Medicare as a secondary payer;

(3) Is enrolled in both Medicare Parts A and B;

(4) Is at least 18 years of age;

(5) Is a United States resident; and

(6) Has a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period.

* * * * *

Multispecialty group means a group as defined at § 414.1305 that consists of clinicians in two or more specialty types or clinicians involved in multiple foci of care.

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Single specialty group means a group that consists of one specialty type or consists of clinicians involved in a single focus of care.

* * * * *

19. Section 414.1305 is amended by—

a. Revising paragraph (6) of the definition for "Attribution-eligible beneficiary";

b. In the definition of "high priority measure", removing the phrase "care coordination, opioid, or

health equity-related quality measure." and adding in its place the phrase "care coordination or opioid-related quality measure"; and

c. Revising the definitions of "Multispecialty group", "MVP participant", and "Single specialty group.

The revisions read as follows:

§414.1305 Definitions.

Attribution-eligible beneficiary

* * *

(6) Has a minimum of one claim for any covered professional service furnished by an eligible clinician who is on the Participation List for an Advanced APM Entity at any determination date during the QP Performance Period.

* * * * *

Multispecialty group means a group that consists of clinicians in two or more specialty types or clinicians involved in multiple foci of care.

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and subsequent years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Single specialty group means a group that consists of clinicians in one specialty type or clinicians involved in a single focus of care.

* * * * *

20. Section 414.1355 is amended by revising paragraph (c)(7) to read as follows:

§ 414.1355 Improvement activities performance category

* * * * *

(c)* * *

(7) Advancing health and wellness, such as MIPS eligible clinicians demonstrating involvement in preventive care and health promotion.

* * * * *

21. Section 414.1365 is amended by adding paragraph (b)(2)(iv) to read as follows:

§ 414.1365 MIPS Value Pathways.

* * * * *

(b) * * *

(2) * * *

(iv) *Self-attestation requirement.* Beginning with the CY 2026 performance period/2028 MIPS payment year, to report an MVP, a group must attest to being either a single-specialty group or a multispecialty group that meets the requirements of a small practice.

* * * * *

22. Section 414.1380 is amended by—

a. Revising paragraphs (b)(1)(i) introductory text, (b)(1)(ii)(D), and (b)(2)(iii) introductory text;

c. Adding paragraph (b)(2)(vi);

d. Revising paragraph (b)(4)(ii)(C); and

e. Adding paragraph (b)(4)(iii).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) *Measure achievement points.* For the CY 2017 through 2022 performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims- based

measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. Except as provided under paragraph (b)(1)(i)(C) of this section, beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) for each such measure. Except as specified otherwise under paragraph (b)(1)(ii) of this section, the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(ii) * * *

(D) *Administrative claims-based quality measure benchmark*.

(*1*) Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS calculates a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period.

(*2*) Beginning with the CY 2025 performance period/2027 MIPS payment year, for each administrative claims-based quality measure, CMS determines 10 benchmark ranges based on the median performance rate of all MIPS eligible clinicians scored on the measure, plus or minus standard deviations.

(*i*) CMS awards achievement points based on which benchmark range a MIPS eligible clinician's performance rate for an administrative claims-based quality measure corresponds; and

(*ii*) CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose performance rate is equal to the median performance for all MIPS eligible clinicians scored on the measure.

(2) * * *

(iii) Excluding cost measure scores calculated for informational-only purposes as provided in paragraph (b)(2)(vi) of this section, the cost performance category score is the sum of the following, not to exceed 100 percent:

* * * * *

(vi) Beginning with the 2028 MIPS payment year, CMS calculates a score for each new cost measure in accordance with the scoring policy set forth in this paragraph (b)(2) of this section for informational-only purposes during the measure's informational-only feedback period.

(A) For the purposes of this paragraph (b)(2)(vi) of this section, the following terms have the following meanings.

(*1*) *New cost measure* means a measure that CMS has newly specified for the MIPS cost performance category for a performance period under § 414.1350 beginning with the 2028 MIPS payment year. This term excludes any cost measures that CMS has specified for the MIPS cost performance category prior to the 2028 MIPS payment year or CMS modifies at any time.

(*2) Informational-only feedback period* means a 2-year period beginning with the first day of the first performance period and ending with the final day of the second performance period for the two applicable MIPS payment years for which CMS initially has specified the new cost measure.

(B) During a new cost measure's informational-only feedback period, CMS does not include any scores for the new cost measure calculated for informational-only purposes under paragraph (b)(2)(vi) of this section in CMS's calculation of a MIPS eligible clinician's cost performance category score under paragraph (b)(2)(iii) of this section or a MIPS eligible clinician's MIPS final score under paragraph (c) of this section.

(C) During a new cost measure's informational-only feedback period, CMS confidentially provides each MIPS eligible clinician their measure score under paragraph (b)(2)(vi) of this section for informational-only purposes. CMS also provides performance feedback to the MIPS eligible clinician in accordance with section 1848(q)(12) of the Act.

(D) Upon completion of a new cost measure's informational-only feedback period, CMS includes its calculation of any scores for the cost measure in CMS's calculation of a MIPS eligible clinician's cost

performance category score under paragraph (b)(2)(iii) of this section and a MIPS eligible clinician's MIPS final score under paragraph (c) of this section.

(3) * * *

(4) * * *

(ii) * * *

(C)(*1*) For the 2019 performance period/2021 MIPS payment year through the 2022 performance period/2024 MIPS payment year, each optional measure is worth 5 or 10 bonus points, as specified by CMS.

(*2*) For the 2023 performance period/2025 MIPS payment year and subsequent years, each optional measure is worth 5 bonus points, as specified by CMS.

(*3*) Beginning with the CY 2026 performance period/2028 MIPS payment years, the total number of bonus points available to be earned when reporting one bonus measure, more than one bonus measure, or all bonus measures is a total of 5 bonus points.

(iii) Beginning with the CY 2026 performance period/2028 MIPS payment year, if certain circumstances occur that impact CMS' assessment of the performance of MIPS eligible clinicians on a measure specified for the Promoting Interoperability performance category under § 414.1375(b), CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS' assessment of performance while allocating the maximum points available or providing full credit for the affected measure as long as the affected measure is reported, resulting in a suppressed measure contributing to the Promoting Interoperability performance category objective score under paragraph (b)(4) of this section; or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. CMS determines whether certain circumstances exist warranting suppression of a measure based on CMS' consideration of one or more of the following factors:

(A) The nature, breadth, and duration of the circumstances' effect on MIPS eligible clinicians' ability to fulfill the measure requirement.

(B) The availability of certified health IT modules to fulfill the measure.

(C) The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

(D) Out-of-date or conflicting technical standards.

(E) Technical and operational capacity of required partners.

(F) Other factors as determined by CMS.

* * * * *

23. Section 414.1400 is amended by—

a. Revising paragraph (b)(1)(ii);

b. In paragraph (d)(3) introductory text, removing the phrase “including:” and adding in its place the phrase "including all of the following:”;

c. Revising paragraph (d)(3)(i);

d. In paragraphs (d)(3)(ii) and (iii), removing the “;” and adding in its place “.”;

e. Redesignating paragraphs (d)(3)(iv) through (vi) as paragraphs (d)(3)(iv) through (vi) introductory text;

f. Adding paragraphs (d)(3)(iv)(A) and (B), (d)(3)(v)(A) and (B), (d)(3)(vi)(A) and (B), and (d)(3)(vii).

g. Revising paragraph (d)(8); and

h. Adding paragraphs (d)(9) and (d)(10).

The revisions and additions read as follows:

§ 414.1400 Third party intermediaries.

* * * * *

(b) * * *

(1) * * *

(ii)(A) Beginning with the CY 2023 performance period/2025 MIPS payment year through the CY 2025 performance period/2027 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data.

(B) Beginning with the CY 2026 performance period/2028 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than 1 year after finalization of the MVP in accordance with the current requirement.

(*1*) QCDRs and qualified registries may also support the APP.

(*2*) A QCDR or qualified registry must support all measures and activities included in the MVP with the following exceptions:

(*i*) If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinicians.

(*ii*) If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

* * * * *

(d) * * *

(3) * * *

(i) At least 3 years of experience administering surveys in which mail survey administration is followed by survey administration via Computer Assisted Telephone Interview (CATI);

(iv) * * *

(A) Beginning January 1, 2024, in addition to administering the survey in English, entities must administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in subregulatory guidance to standardize the CAHPS data collection process for MIPS and to make sure the survey data collected across survey vendors are comparable within the program or model;.

(B) [Reserved]

(v) * * *

(A) Beginning January 1, 2027, use equipment, software, computer programs, systems, and facilities that can send survey invitations via email that include a patient-specific hyperlink to a web survey, collect data via web, and track cases from web surveys through telephone follow-up activities.

(B) [Reserved]

(vi) * * *

(A) Beginning January 1, 2027, employ a web survey administrator.

(B) [Reserved]

(vii) Beginning January 1, 2027, at least 3 years of experience administering surveys in which web survey administration is followed by survey administration via mail survey or Computer Assisted

Telephone Interview (CATI).

* * * * *

(8) From January 1, 2019 through December 31, 2025, the entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(9) Beginning with January 1, 2026, the entity seeking to be a CMS-approved survey vendor must include on its application the range of costs of its third-party intermediary services.

(10) Beginning with the CY 2027 performance period/2029 MIPS payment year, the CMS-approved survey vendor must administer the survey via a web-mail-phone protocol.

* * * * *

24. Section 414.1405 amended by adding paragraph (b)(10)(ii) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(10) * * *

(i) * * *

(ii) The performance threshold for the 2028 through 2030 MIPS payment years is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

§ 414.1415 [Amended]

25. Section 414.1415 is amended in paragraph (c)(7) by removing the phrase “2023 QP Performance Period, notwithstanding” and adding in its place the phrase “2023 QP Performance Period and ending with the 2025 QP Performance Period, notwithstanding”.

§ 414.1420 [Amended]

26. Section 414.1420 is amended in paragraph (d)(8) by removing the phrase “2023 QP Performance Period, notwithstanding” and adding in its place the phrase “2023 QP Performance Period and ending with the 2025 QP Performance Period, notwithstanding”.

* * * * *

27. Section 414.1425 is amended by –

(a) Adding paragraph (b)(3); and

(b) Revising paragraphs (c)(3), (c)(4), (d)(1), and (2).

The addition and revisions read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(b) * * *

(3) For QP Performance Periods beginning with 2026, except for paragraphs (b)(1) and (b)(2) of this section and as set forth in § 414.1440, for purposes of the QP determinations, CMS performs QP determinations for the eligible clinicians three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a date (March 31, June 30, or August 31) CMS uses based on participation in the Advanced APM.

(c) * * *

(3) An eligible clinician is a QP for a year under the Medicare Option if--

(i) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, the eligible clinician is in an APM Entity group that achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(1) and (3).

(ii) Beginning with the CY 2026 QP Performance Period, the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold

Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(1) and (3).

(4) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, notwithstanding paragraph (c)(3) of this section, an eligible clinician is a QP for a year if--

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the QP payment amount threshold or the QP patient count threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the QP payment amount threshold or the QP patient count threshold.

* * * * *

(d) * * *

(1) An eligible clinician is a Partial QP for a year under the Medicare Option if:

(i) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, the eligible clinician is in an APM Entity group that achieves Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the eligible clinician achieves individually, or as part of an APM Entity group, a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(2) and (4).

(ii) Beginning with the CY 2026 QP Performance Period, the eligible clinician individually, or as part of an APM Entity group, achieves a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the eligible clinician achieves individually, or as part of an APM Entity group, a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold

or Partial QP patient count threshold for that QP Performance Period as described in § 414.1430(b)(2) and (4).

(2) Starting with the CY 2017 QP Performance Period and ending with the CY 2025 QP Performance Period, notwithstanding paragraph (d)(1) of this section, an eligible clinician is a Partial QP for a year if--

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the corresponding QP or Partial QP threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the corresponding Partial QP Threshold.

* * * * *

28. Section 414.1435 is revised to read as follows:

§ 414.1435 Qualifying APM participant determination: Medicare option.

* * * * *

(a) *Payment amount method.* For QP performance periods through 2025, the Threshold Score for an APM Entity or eligible clinician is calculated as a percent by dividing the value described under paragraph (a)(1) of this section by the value described under paragraph (a)(2) of this section.

(1) *Numerator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period.

(2) *Denominator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all attribution-eligible beneficiaries during the QP Performance Period.

(3) *Claims and adjustments.* In the calculations under paragraphs (a)(1) and (2) of this section, CMS compiles claims and treats claims adjustments, supplemental service payments, and alternative payment methods in the same manner as described in § 414.1450.

(b) *Patient count method.* For QP performance periods through 2025, the Threshold Score for each eligible clinician in an APM Entity group is calculated as a percent under the patient count method

by dividing the value described under paragraph (b)(1) of this section by the value described under paragraph (b)(2) of this section.

(1) *Numerator.* The number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(2) *Denominator.* The number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(3) *Unique beneficiaries.* For each APM Entity group, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times.* Based on attribution under the terms of an Advanced APM, a single Medicare beneficiary may be counted in the numerator or denominator for multiple different APM Entity groups.

(2) When operationally feasible, this attributed beneficiary list will be the final beneficiary list used for reconciliation purposes in the Advanced APM.

(3) When it is not operationally feasible to use the final attributed beneficiary list, the attributed beneficiary list will be taken from the Advanced APM's most recently available attributed beneficiary list at the end of the QP Performance Period.

(c) *Covered Professional Service Payment amount method.* Starting with the 2026 QP performance period, the Threshold Score for an APM Entity or eligible clinician is calculated as a percent by dividing the value described under paragraph (c)(1) of this section by the value described under paragraph (c)(2) of this section.

(1) *Numerator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period.

(2) *Denominator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all Covered Professional Service attribution-eligible beneficiaries during the QP Performance Period.

(3) *Claims and adjustments.* In the calculations under paragraphs (c)(1) and (2) of this section, CMS compiles claims and treats claims adjustments, supplemental service payments, and alternative payment methods in the same manner as described in § 414.1450.

(d) *Covered Professional Service Patient count method.* Starting with the 2026 QP performance period the Threshold Score for each eligible clinician in an APM Entity group is calculated as a percent under the patient count method by dividing the value described under paragraph (e)(1) of this section by the value described under paragraph (d)(2) of this section.

(1) *Numerator.* The number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(2) *Denominator.* The number of Covered Professional Service attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(3) *Unique beneficiaries.* For each APM Entity group, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times.* Based on attribution under the terms of an Advanced APM, a single Medicare beneficiary may be counted in the numerator or denominator for multiple different APM Entity groups.

(e) *E/M Payment amount method.* Starting with the 2026 QP performance period, the Threshold Score for an APM Entity or eligible clinician is calculated as a percent by dividing the value described under paragraph (e)(1) of this section by the value described under paragraph (e)(2) of this section.

(1) *Numerator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the QP Performance Period.

(2) *Denominator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to all E/M attribution-eligible beneficiaries during the QP Performance Period.

(3) *Claims and adjustments.* In the calculations under paragraphs (e)(1) and (2) of this section, CMS compiles claims and treats claims adjustments, supplemental service payments, and alternative payment methods in the same manner as described in § 414.1450.

(f) *E/M Patient count method.* Starting with the 2026 QP performance period, the Threshold Score for each eligible clinician in an APM Entity group is calculated as a percent under the patient count method by dividing the value described under paragraph (f)(1) of this section by the value described under paragraph (f)(2) of this section.

(1) *Numerator.* The number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(2) *Denominator.* The number of E/M attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnish Medicare Part B covered professional services or services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the QP Performance Period.

(3) *Unique beneficiaries.* For each APM Entity group, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times.* Based on attribution under the terms of an Advanced APM, a single Medicare beneficiary may be counted in the numerator or denominator for multiple different APM Entity groups.

(g) *Attribution.*

(1) Attributed beneficiaries are determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology except as set forth in paragraph (g)(1) of this section.

(i) Beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

(ii) [Reserved]

(2) When operationally feasible, this attributed beneficiary list will be the final beneficiary list used for reconciliation purposes in the Advanced APM.

(3) When it is not operationally feasible to use the final attributed beneficiary list, the attributed beneficiary list will be taken from the Advanced APM's most recently available attributed beneficiary list at the end of the QP Performance Period.

(h) *Use of methods*. CMS calculates Threshold Scores for an APM Entity or eligible clinician as provided by § 414.1425(b) under all payment amount and patient count methods for each QP Performance Period. CMS then assigns to the eligible clinicians included in the APM Entity group or to the eligible clinician the score that results in the greater QP status. QP status is greater than Partial QP status, and Partial QP status is greater than no QP status.

* * * * *

29. Section 414.1455 is amended by revising paragraph (b)(3)(ii) and (vi) to read as follows:

§ 414.1455 Limitation on review.

* * * * *

(b) * * *

(3) * * *

(ii) All requests for targeted review must be submitted during the targeted review request submission period as described at § 414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

* * * * *

(vi) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 15 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

30. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

31. Section 424.205 amended by revising paragraphs (c)(10), (f)(2)(i), and (f)(5) to read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(c) * * *

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) 16 in-person, distance learning, or Online core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first core session.

(ii) One in-person, distance learning, or Online core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

* * * * *

(f) * * *

(1) * * *

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, MBI, and age.

* * * * *

(2) * * *

(i) Documentation of the type of session (in-person, distance learning, or Online).

* * * * *

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has achieved required minimum weight loss as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that

supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(ii) Has achieved required minimum weight loss as measured in accordance with § 410.79(c)(ii) during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

(iv) Has achieved at least a 9-percent weight loss percentage as measured in in accordance with § 410.79(c)(ii) during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

32. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

33. Section 425.20 is amended by revising paragraph (1)(ii) in the definition of "Beneficiary eligible for Medicare CQMs" to read as follows:

§ 425.20 Definitions.

* * * * *

Beneficiary eligible for Medicare CQMs * * *

(1) * * *

(ii)(A) For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(B) For performance year 2025 and subsequent performance years, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

34. Section 425.110 is amended by revising paragraph (a)(2) and adding paragraph (a)(3) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

(a) * * *

(2) For agreement periods beginning before January 1, 2027, CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. In the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries.

(3) For agreement periods beginning on or after January 1, 2027, CMS determines whether an ACO has 5,000 or more beneficiaries historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. In the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries.

(i) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in the third benchmark year.

(ii) If an ACO has fewer than 5,000 assigned beneficiaries in either the first benchmark year, the second benchmark year, or both, the ACO may only participate under the BASIC track in accordance with § 425.600(h)(3).

* * * * *

35. Section 425.118 is amended by—

a. Redesignating paragraph (b)(3) as paragraph (b)(4);

b. Adding new paragraph (b)(3); and

c. In newly redesignated paragraph (b)(4) adding paragraph (b)(4)(iii).

The additions read as follows:

§ 425.118 Required reporting of ACO participants and ACO providers/suppliers.

* * * * *

(b) * * *

(3) *Change of ownership for ACO participant.* No later than 30 days after an ACO participant has undergone a change of ownership that has resulted in a change to its Medicare enrolled TIN, whereby the surviving Medicare enrolled TIN has no Medicare billing claims history, the ACO must submit a change request to CMS.

(i) The change request and supporting documentation must be submitted in the form and manner specified by CMS.

(ii)(A) CMS has sole discretion to approve the change request.

(B) If CMS approves the change request, the ACO participant TIN is updated in the ACO participant list in the form and manner specified by CMS.

(4) * * *

(iii) In alignment with changes approved under paragraph (b)(3) of this section, CMS adjusts the ACO's assignment, performance year financial calculations, and the requirement that the ACO submit quality data under § 425.508 and § 425.510 on behalf of eligible professionals that bill under the TIN of an ACO participant. When processed during applicable Quality Payment Program snapshot dates for the relevant Performance Period, the adjustment includes the surviving Medicare enrolled TIN with no Medicare billing claims history on the ACO participant list as the change becomes effective during the performance year.

* * * * *

36. Section 425.224 is amended by revising paragraph (b)(1)(ii)(A) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) Whether the ACO demonstrated a pattern of failure to meet both the quality performance

standard and alternative quality performance standard (if applicable) or met any of the criteria for termination under § 425.316(c)(1)(ii), (c)(2)(ii), or (c)(3)(ii).

* * * * *

37. Section 425.316 is amended by revising paragraph (c)(2) introductory text and adding paragraph (c)(3) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(c) * * *

(2) *For performance years beginning on or after January 1, 2021 and before January 1, 2026.*

* * * * *

(3) *For performance years beginning on or after January 1, 2026.*

(i) If the ACO fails to meet both the quality performance standard and the alternative quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS terminates an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet both the quality performance standard and the alternative quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet both the quality performance standard and the alternative quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet both the quality performance standard and the alternative quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet both the quality performance standard and the alternative quality performance standard for 2 consecutive performance years across 2 agreement

periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

* * * * *

38. Section 425.400 is amended by revising paragraph (c)(1)(ix) introductory text and adding paragraph (c)(1)(x) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(ix) For the performance year starting on January 1, 2025, as follows:

* * * * *

(x) For the performance year starting on January 1, 2026, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 98016 (code for virtual check-in).

(*5*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*6*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*7*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*8*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary

care service code under this paragraph (c)(1)(x)).

(*10*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*11*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*12*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*13*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*14*) 99439 (code for non-complex chronic care management).

(*15*) 99452 (code for interprofessional consultation service).

(*16*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*17*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*18*) 99495 and 99496 (codes for transitional care management services).

(*19*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for physical activity and nutritional assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G0537 and G0538 (codes for cardiovascular risk assessment and risk management services).

(*14*) G0539 and G0540 (codes for individual behavior management/modification caregiver

training services).

(*15*) G0541, G0542, and G0543 (codes for direct care caregiver training services).

(*16*) G0544 (code for post-discharge telephonic follow-up contacts intervention).

(*17*) G0556, G0557, and G0558 (codes for advanced primary care management services).

(*18*) G0560 (code for safety planning interventions).

(*19*) G0568 and G0569 (codes for behavioral health integration add-on when furnished with advanced primary care management services).

(*20*) G0570 (code for psychiatric collaborative care model add-on when furnished with advanced primary care management services).

(*21*) G2010 (code for the remote evaluation of patient video/images).

(*22*) G2012 and G2252 (codes for virtual check-in).

(*23*) G2058 (code for non-complex chronic care management).

(*24*) G2064 and G2065 (codes for principal care management services).

(*25*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*26*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*27*) G2214 (code for psychiatric collaborative care model).

(*28*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(x)(A) of this section or a HCPCS code specified in paragraph (c)(1)(x)(B) of this section, when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

39. Section 425.512 is amended by—

a. In paragraph (a)(3)(i), removing the phrase “quality performance score” and adding in its place the phrase “quality score”;

b. In paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B)(*1*), (a)(5)(i)(C)(*1*), and (a)(7), removing the phrase “health equity adjusted quality performance score” and adding in its place the phrase “quality

score";

c. Revising and republishing paragraph (b);

d. Revising paragraph (c)(1) introductory text;

e. Adding paragraph (c)(1)(iii);

f. In paragraphs (c)(2)(i), (c)(2)(ii), and (c)(3)(i), removing the phrase "quality performance score" and adding in its place the phrase "quality score"; and

g. In paragraphs (c)(3)(ii), (c)(3)(iii), and (c)(3)(iv), removing the phrase "health equity adjusted quality performance score" and adding in its place the phrase "quality score".

The revisions and addition read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

* * * * *

(b) *Calculation of an adjustment to an ACO's quality score for performance years 2023 through 2025* —

(1) *For performance year 2023.* For an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, CMS calculates the ACO's quality score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's population and income adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(2) *For performance year 2024.* For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's quality score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's population and income adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(3) *For performance year 2025.* For an ACO that reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all of the required measures in the APP Plus quality measure set, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's quality score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's population and income adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(4) *Calculation of ACO's population and income adjustment bonus points.* CMS calculates the ACO's bonus points as follows:

(i) For each measure that an ACO is required to report for the applicable performance year, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(4)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates a multiplier for the ACO.

(A) (*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D

low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(4)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance years 2024 and 2025, the proportion of the ACO's assigned beneficiaries with any months enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

(B) If the proportion determined in accordance with paragraph (b)(4)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for bonus points.

(v) Except as specified in paragraph (b)(4)(iv)(B) of this section, CMS calculates the ACO's bonus points as the product of the measure performance scaler determined under paragraph (b)(4)(iii) of this section and the multiplier determined under paragraph (b)(4)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's bonus points is set equal to 10.

(5) *Use of ACO's quality score.* The ACO's quality score, determined in accordance with paragraphs (b)(1) through (4) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B), and (a)(7) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with § 425.605(d), and under the ENHANCED track in accordance with § 425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with § 425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i), and (a)(5)(i) of this section or the alternative quality performance standard established in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iv) In determining the quality score for an ACO affected by extreme and uncontrollable

circumstances as described in paragraphs (c)(3)(ii) through (iv) of this section (as applicable).

(c) * * *

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on any of the following:

* * * * *

(iii) For performance year 2025 and subsequent performance years, the ACO, as defined at § 425.20, is affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program.

* * * * *

40. Section 425.600 is amended by—

a. In paragraph (a)(4)(i)(C)(*1*), removing the phrase "paragraph (g)(1) of this section" and adding in its place the phrase "paragraphs (g)(1) or (h)(1) of this section";

b. In paragraph (a)(4)(i)(C)(*2*)(*iii*), removing the phrase "paragraph (h)(2)(i) of this section" and adding in its place the phrase "paragraph (i)(2)(i) of this section";

c. In paragraph (a)(4)(ii), removing the phrase "paragraph (d) or paragraph (g)(2) of this section" and adding in its place the phrase "paragraphs (d), (g)(2) or (h) of this section";

d. Revising paragraph (g) introductory text;

e. Redesignating paragraph (h) as paragraph (i); and

f. Adding new paragraph (h).

The revision and addition read as follows:

§ 425.600 Selection of risk model.

* * * * *

(g) For agreement periods beginning on or after January 1, 2024 and before January 1, 2027, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

* * * * *

(h) For agreement periods beginning on or after January 1, 2027, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section

as follows:

(1) If an ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section, except as otherwise specified in paragraph (h)(3) of this section.

(i) An ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate under the BASIC track's glide path for a maximum of one agreement period, as specified in paragraph (a)(4)(i)(C) of this section.

(ii) An ACO that enters an agreement period under the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section is deemed to have completed one agreement period under the BASIC track's glide path. For the purpose of determining the ACO's prior participation in the BASIC track's glide path, CMS considers whether the ACO satisfies either of the following:

(A) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track's glide path.

(B) For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track's glide path.

(iii) An ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives but is not eligible to enter the BASIC track's glide path, in accordance with this paragraph, may enter BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section, except as otherwise specified in paragraph (h)(3) of this section.

(2) If an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period, or the ENHANCED track under paragraph (a)(3) of this section, except as otherwise specified in paragraph (h)(3) of this section.

(3) If an ACO is determined to have fewer than 5,000 assigned beneficiaries in either the first

benchmark year, the second benchmark year, or both, in accordance with § 425.110(a)(3), the ACO may only enter the BASIC track. The ACO may enter a level of risk and potential reward under the BASIC track in accordance with the requirements of this paragraph, as follows:

(i) An ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives may enter the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section (if eligible in accordance with paragraph (h)(1) of this section), or BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period.

(ii) An ACO determined to be experienced with performance-based risk Medicare ACO initiatives may enter BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section for all performance years of the agreement period.

* * * * *

41. Section 425.605 is amended by—

a. In paragraph (b)(2)(ii)(E), removing the reference "§ 425.600(h)(2)" and adding in its place the reference "§ 425.600(i)(2)";

b. In paragraph (d)(1) introductory text, removing the references "§ 425.600(d) or § 425.600(g)" and adding in its place the references "§ 425.600(d), (g), or (h)";

c. In paragraphs (d)(1)(i)(A)(*3*)(*ii*), (d)(1)(i)(A)(*4*)(*ii*), (d)(1)(ii)(A)(*3*)(*ii*), (d)(1)(ii)(A)(*4*)(*ii*), (d)(1)(iii)(A)(*3*)(*ii*), (d)(1)(iii)(A)(*4*)(*ii*), (d)(1)(iv)(A)(*3*)(*ii*), (d)(1)(iv)(A)(*4*)(*ii*), (d)(1)(v)(A)(*3*)(*ii*), and (d)(1)(v)(A)(*4*)(*ii*), removing the phrase "health equity adjusted quality performance score calculated according to § 425.512(b)" and adding in its place the phrase "quality score calculated according to § 425.512";

d. Revising paragraph (d)(2);

e. Adding paragraph (f)(2)(ii);

f. Revising paragraph (f)(3) introductory text;

g. Removing the punctuation "; and" at the end of paragraph (f)(3)(i) and adding in its place a period;

h. Adding paragraph (f)(3)(iii);

i. Redesignating paragraph (f)(4) as paragraph (f)(5);

j. Adding new paragraph (f)(4); and

k. Adding paragraphs (h)(1)(v) and (i).

The revisions and additions read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(d) * * *

(2) If the ACO enters the BASIC track at Level E as specified under § 425.600(d), (g), or (h), the level of risk and reward specified in paragraph (d)(1)(v) of this section applies to all performance years of an ACO's agreement period.

* * * * *

(f) * * *

(2) * * *

(ii) For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area.

(3) CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):

* * * * *

(iii) The time period during which the ACO was affected by a cyberattack, including ransomware/malware.

(4) CMS determines the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

(i) CMS uses the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

(ii) Except as specified in paragraph (f)(4)(iii) of this section, if no end date is indicated on the ACO's application or otherwise provided to CMS in a form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, CMS applies a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

(iii) If the start date indicated on the ACO's application described in paragraph (f)(4)(i) of this section is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (f)(4)(i) of this section, CMS applies an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

* * * * *

(h) * * *

(1) * * *

(v) For agreement periods beginning on or after January 1, 2027, the ACO has at least 5,000 assigned beneficiaries in each of the ACO's benchmark years.

* * * * *

(i) *Calculation of performance payment limit and loss recoupment limit.*

(1) The performance payment limit is a percentage of the ACO's updated benchmark, as determined under § 425.601 or § 425.652.

(i) CMS calculates the performance payment limit as follows, except as specified in paragraph (i)(1)(ii) of this section:

(A) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the performance year.

(B) Calculates the product of the percentage specified in paragraph (d)(1)(i)(B)(*2*), (d)(1)(ii)(B)(*2*), (d)(1)(iii)(B)(*2*), (d)(1)(iv)(B)(*2*), and (d)(1)(v)(B)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(1)(i)(A) of this section.

(ii) For agreement periods beginning on or after January 1, 2027, if the ACO has fewer than 5,000

assigned beneficiaries in benchmark year (BY) 1, BY2 or BY3, in conducting financial reconciliation for each performance year, CMS determines whether to apply an alternative performance payment limit, rather than the performance payment limit specified in paragraph (d)(1)(i)(B)(*2*), (d)(1)(ii)(B)(*2*), (d)(1)(iii)(B)(*2*), (d)(1)(iv)(B)(*2*), and (d)(1)(v)(B)(*2*) of this section, as applicable, as follows:

(A) CMS calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries.

(B) CMS calculates the product of the percentage specified in paragraph (d)(1)(i)(B)(*2*), (d)(1)(ii)(B)(*2*), (d)(1)(iii)(B)(*2*), (d)(1)(iv)(B)(*2*), and (d)(1)(v)(B)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(1)(ii)(A) of this section.

(C) The performance payment limit is set to the lesser of the amount calculated under paragraph (i)(1)(i)(B) of this section and the alternative amount calculated under paragraph (i)(1)(ii)(B) of this section.

(2) The loss recoupment limit is a percentage of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO (revenue-based loss recoupment limit) not to exceed a percentage of the ACO's updated benchmark as determined under § 425.601 or § 425.652 (benchmark-based loss recoupment limit).

(i) CMS calculates the benchmark-based loss recoupment limit as follows, except as specified in paragraph (i)(2)(ii) of this section:

(A) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the performance year.

(B) Calculates the product of the percentage used to calculate the benchmark-based loss recoupment limit specified in paragraph (d)(1)(iii)(D)(*2*), (d)(1)(iv)(D)(*2*), and (d)(1)(v)(D)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(2)(i)(A) of this section.

(ii) For agreement periods beginning on or after January 1, 2027, if the ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2 or BY3, in conducting financial reconciliation for each performance

year, CMS determines whether to apply an alternative loss recoupment limit, as follows:

(A) CMS calculates an alternative benchmark-based loss recoupment limit:

(*1*) CMS calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries.

(*2*) CMS calculates the product of the percentage used to calculate the benchmark-based loss recoupment limit specified in paragraph (d)(1)(iii)(D)(*2*), (d)(1)(iv)(D)(*2*), and (d)(1)(v)(D)(*2*) of this section, as applicable, and the ACO's total benchmark expenditures calculated according to paragraph (i)(2)(ii)(A)(*1*) of this section.

(B) The loss recoupment limit is set to the revenue-based loss recoupment limit specified in paragraph (d)(1)(iii)(D)(*1*), (d)(1)(iv)(D)(*1*), or (d)(1)(v)(D)(*1*) of this section, as applicable, not to exceed the lower of the benchmark-based loss recoupment limit amount calculated under paragraph (i)(2)(i)(B) of this section or the alternative benchmark-based loss recoupment limit amount calculated under paragraph (i)(2)(ii)(A)(*2*) of this section.

42. Section 425.610 is amended by—

a. In paragraphs (d)(3)(ii), (d)(4)(ii), (f)(3)(i)(A), and (f)(4)(i)(A), removing the phrase "health equity adjusted quality performance score calculated according to § 425.512(b)" and adding in its place the phrase "quality score calculated according to § 425.512";

b. Adding paragraph (i)(2)(ii);

c. Revising paragraph (i)(3) introductory text;

d. Removing the punctuation "; and" at the end of paragraph (i)(3)(i) and adding in its place a period;

e. Adding paragraph (i)(3)(iii);

f. Redesignating paragraph (i)(4) as paragraph (i)(5); and

g. Adding new paragraphs (i)(4) and (l).

The revisions and additions read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(i) * * *

(2) * * *

(ii) For performance year 2025 and subsequent performance years, for an ACO as defined at § 425.20 that is determined to be affected by an extreme and uncontrollable circumstance due to a cyberattack, including ransomware/malware, for any month of the performance year that is affected, CMS considers 100 percent of the ACO's assigned beneficiaries to reside in an affected area.

(3) CMS applies determinations made under the Quality Payment Program with respect to all of the following (as applicable):

* * * * *

(iii) The time period during which the ACO was affected by a cyberattack, including ransomware/malware.

(4) CMS determines the time period during which an ACO is affected by a cyberattack, including ransomware/malware, as follows:

(i) CMS uses the start and end date indicated on an ACO's application to the Quality Payment Program for an extreme and uncontrollable circumstance exception due to a cyberattack, including ransomware/malware, or the start date indicated on the application and an end date subsequently provided by the ACO in the form and manner as specified by CMS.

(ii) Except as specified in paragraph (i)(4)(iii) of this section, if no end date is indicated on the ACO's application or otherwise provided to CMS in a form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS applies a 90-day duration for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

(iii) If the start date indicated on the ACO's application described in paragraph (i)(4)(i) of this section is less than 90 days before the end of the performance year and no end date is indicated on the ACO's application or otherwise provided to CMS in the form and manner specified by CMS, described in paragraph (i)(4)(i) of this section, CMS applies an end date of December 31st of the performance year for purposes of determining the time period during which the ACO was affected by the extreme and uncontrollable circumstance.

* * * * *

(l) *Calculation of performance payment limit and loss recoupment limit.*

(1) The performance payment limit and the loss recoupment limit are a percentage of the ACO's updated benchmark.

(2) CMS calculates the performance payment limit and loss recoupment limit as follows, except as specified in paragraph (l)(3) of this section:

(i) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the performance year.

(ii) Calculates the product of the percentage used to calculate the performance payment limit specified in paragraph (e)(2) of this section or the loss recoupment limit specified in paragraph (g) of this section and the ACO's total benchmark expenditures calculated according to paragraph (l)(2)(i) of this section.

(3) For agreement periods beginning on or after January 1, 2027, if the ACO has fewer than 5,000 assigned beneficiaries in BY1, BY2 or BY3, in conducting financial reconciliation for each performance year, CMS determines whether to apply an alternative performance payment limit or alternative loss recoupment limit, rather than the performance payment limit specified in paragraph (e)(2) of this section or the loss recoupment limit specified in paragraph (g) of this section, as follows:

(i) CMS calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year and an ACO's assigned beneficiary person years for the benchmark year with the lowest number of assigned beneficiaries.

(ii) CMS calculates the product of the percentage used to calculate the performance payment limit specified in paragraph (e)(2) of this section or the loss recoupment limit specified in paragraph (g) of this section and the ACO's total benchmark expenditures calculated according to paragraph (l)(3)(i) of this section.

(iii) The performance payment limit or loss recoupment limit is set to the lesser of the amount calculated under paragraph (l)(2)(ii) of this section or the alternative amount calculated under paragraph (l)(3)(ii) of this section.

43. Section 425.612 is amended by revising paragraph (a)(1)(i)(B) to read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(i) * * *

(B)*(1)* A list of SNFs, including the Medicare-enrolled TIN and the CCN, with whom the ACO will partner along with executed written SNF affiliate agreements between the ACO and each listed SNF.

(*2*) An ACO must notify CMS no later than 30 days after the change of ownership of a SNF affiliate, identified in accordance with paragraph (a)(1)(i)(B)(*1*) of this section, that has resulted in a change to the Medicare enrolled TIN of the SNF affiliate. Such notice and supporting documentation must be submitted in the form and manner specified by CMS.

* * * * *

§ 425.652 [Amended]

44. Section 425.652 is amended by—

a. In paragraph (a)(8)(ii)(A), removing the phrase "health equity benchmark adjustment (HEBA)" and adding in its place the phrase "population adjustment";

b. In paragraphs (a)(8)(ii)(B) introductory text, (a)(8)(ii)(B)(*2*), and (a)(9)(vi), removing the phrase "HEBA" and adding in its place the phrase "population adjustment"; and

c. In paragraph (a)(9)(v), removing the phrase "HEBA scaler used in calculating the HEBA under § 425.662(b)(2)" and adding in its place the phrase "scaler used in calculating the population adjustment under § 425.662(b)(2)".

§ 425.658 [Amended]

45. Section 425.658 is amended in paragraph (d) by removing the phrase "HEBA" and adding in its place the phrase "population adjustment".

45. Section 425.662 is amended by—

a. Revising the section heading and paragraph (a);

b. In paragraph (b) introductory text, removing the phrase "health equity benchmark adjustment" and adding in its place the phrase "population adjustment";

c. In paragraph (b)(2), removing the phrase "Calculates the HEBA scaler" and adding in its place

the phrase “Calculates a scaler”; and

d. Revising paragraphs (b)(3), (b)(4), and (c).

The revisions read as follows:

§ 425.662 Calculating the population adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates the population adjustment to the historical benchmark.

(b) * * *

(3) Determines the ACO's eligibility for the population adjustment based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is only eligible for the population adjustment if this proportion is greater than or equal to 15 percent. An ACO with a proportion less than 15 percent is ineligible to receive the population adjustment.

(4) Calculates the population adjustment. If the ACO is eligible for the population adjustment as determined in paragraph (b)(3) of this section, the adjustment is equal to the product of the scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

(c) *Applicability of the population adjustment.* CMS compares the population adjustment determined in paragraph (b)(4) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the per capita prior savings adjustment determined in § 425.658(c), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8)(ii).

§ 425.672 [Amended]

47. Section 425.672 is amended in paragraph (c)(2)(iv) by removing the phrase “and calculating the HEBA scaler” and adding in its place the phrase “and calculating the scaler”.

PART 427--MEDICARE PART B DRUG INFLATION REBATE PROGRAM

48. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w-3a(i), 1302, and 1395hh.

49. Section 427.20 is amended by removing the definition of "Billing and payment code FDA approval or licensure date".

50. Section 427.302 is amended by—

a. Revising paragraphs (c) introductory text and (c)(5);

b. Adding paragraph (c)(6); and

c. Revising paragraphs (d)(1).

The revisions and addition to read as follows:

§ 427.302 Calculation of the per unit Part B rebate amount.

* * * * *

(c) *Identification of the payment amount benchmark quarter*. For each Part B rebatable drug, CMS identifies the applicable payment amount benchmark quarter as set forth in paragraphs (c)(1) through (3) of this section, as applicable, subject to paragraphs (c)(4) through (6) of this section, using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, and using the earliest approval or licensure date of any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed.

* * * * *

(5) If the data needed to calculate the payment amount in the payment amount benchmark quarter described in and determined under § 427.302(d)(1) are not available, CMS uses the third full calendar quarter after a drug is assigned a billing and payment code as the payment amount benchmark quarter, no earlier than the calendar quarter beginning July 1, 2021, or the third full calendar quarter after the drug's first marketed date, whichever is later.

(6) For a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case of a Part B rebatable drug that is no longer considered to be a selected drug, for each applicable quarter beginning after the price applicability period with respect to the drug, the payment amount benchmark quarter is the calendar quarter beginning January 1 of the last year during the price applicability period

with respect to the selected drug.

(d) * * *

(1) For a Part B rebatable drug, subject to paragraphs (d)(1)(i) and (ii) of this section and except as provided in paragraph (d)(2) of this section, CMS identifies the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter.

(i) If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS calculates the payment amount in the payment amount benchmark quarter using positive ASP or positive WAC data from the ASP Data Collection System.

(ii) If a published payment limit is not available and neither positive ASP nor positive WAC data are available in the ASP Data Collection System, CMS calculates the payment amount in the payment amount benchmark quarter using WAC data from other public sources.

* * * * *

51. Section 427.501 is amended by adding paragraph (c)(3) to read as follows:

§ 427.501 Rebate Reports and reconciliation.

* * * * *

(c) * * *

(3) The manufacturer's rebate amount due is reported as a dollar amount rounded to the nearest cent.

* * * * *

52. Section 427.502 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 427.502 Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024.

* * * * *

(c) * * *

(1) * * *

(ii) Within 9 months after issuance of the single Rebate Report, CMS performs one regular reconciliation for the applicable calendar quarters in calendar year 2024 in order to include revisions to the information used, determined under § 427.501(b)(1), to calculate the rebate amount. The

reconciliation is as determined under § 427.501(d) inclusive of a preliminary reconciliation and a report with the reconciled rebate amount.

PART 428--MEDICARE PART D DRUG INFLATION REBATE PROGRAM

53. The authority citation for part 428 continues to read as follows:

Authority: 42 U.S.C. 1395w-114b, 1302, and 1395hh.

54. Section 428.401 is amended by adding paragraph (c)(3) to read as follows:

§ 428.401 Rebate Reports and reconciliation.

* * * * *

(c) * * *

(3) The manufacturer's rebate amount due is reported as a dollar amount rounded to the nearest cent.

§ 428.402 [Amended]

55. Section 428.402 is amended by—

a. In paragraph (c)(1)(ii), removing the phrase "will be reconciled 21 months" and adding in its place the phrase "is reconciled within 21 months"; and

b. In paragraph (c)(2)(ii) removing the phrase "will be reconciled 9 months after the Rebate Report and 33 months after" and adding in its place the phrase "within 9 months after the Rebate Report and within 33 months after".

§ 428.405 [Amended]

56. Section 428.405 is amended in paragraph (a)(1) introductory text by removing the phrase "30 calendar days" and adding in its place the phrase "30th calendar day".

PART 495--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

58. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

59. Section 495.24 by adding paragraph (f)(3) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(f) * * *

(3) Beginning with the EHR reporting period in CY 2026, if certain circumstances occur that impact CMS's assessment of the performance of eligible hospitals and CAHs on a measure selected as described in paragraph (f)(1)(i)(A) of this section, CMS may, in its sole discretion, suppress the affected measure by excluding it from CMS' assessment of performance while allocating the maximum points available or providing full credit for the affected measure as long as the affected measure is reported, resulting in a suppressed measure contributing to the Medicare Promoting Interoperability Program objective score in paragraph (f)(1)(i)(D) of this section; or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. CMS determines whether certain circumstances exist warranting suppression of a measure based on CMS' consideration of one or more of the following factors:

(i) The nature, breadth, and duration of the circumstance's effect on eligible hospitals' and CAHs' ability to fulfill the measure requirement.

(ii) The availability of certified health IT modules to fulfill the measure.

(iii) The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

(iv) Out-of-date or conflicting technical standards.

(v) Technical and operational capacity of required partners.

(vi) Other factors as determined by CMS.

* * * * *

PART 512--STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR THE RADIATION ONCOLOGY MODEL AND THE END-STAGE RENAL DISEASE TREATMENT CHOICES MODEL

60. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

61. Adding subparts F and G to part 512 to read as follows:

Subpart F—[Reserved]
Subpart G—Ambulatory Specialty Model (ASM)
General
512.700Basis and scope.

512.705Definitions.
512.710Participant eligibility and selection.
Performance Categories and Scoring
512.715Overview of performance assessment.
512.720Data submission requirements.
512.725Quality ASM performance category.
512.730Cost ASM performance category.
512.735Improvement activities ASM performance category.
512.740Promoting Interoperability ASM performance category.
512.745Final scoring.
Payment and Timely Error Notice Process
512.750Payment adjustment.
512.755Timely error notice.
Data Sharing, Waivers, Safe Harbor, and Compliance
512.760Data sharing with ASM participants.
512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.
512.770ASM beneficiary incentives.
512.771Collaborative care arrangements.
512.775Medicare program waivers.
512.780Extreme and uncontrollable circumstances.

Subpart G—Ambulatory Specialty Model (ASM)

§ 512.700 Basis and scope of subpart.

(a) *Basis.* This subpart implements the test of the Ambulatory Specialty Model (ASM) under section 1115A of the Act.

(b) *Scope.* This subpart sets forth the following:

(1) The method for selecting ASM participants.

(2) The methodology for ASM participant performance assessment and scoring for purposes of the improvement activities ASM performance category, quality ASM performance category, cost ASM performance category, and Promoting Interoperability ASM performance category, including beneficiary inclusion and episode-based cost measures.

(3) Data submission for applicable ASM performance categories.

(4) The schedule and methodologies for payment adjustments.

(5) Appeals process.

(6) Data sharing with ASM participants.

(7) ASM beneficiary incentives.

(8) Collaborative care arrangements.

(9) Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(10) Medicare program waivers.

(11) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) *Applicability.* Except as otherwise specified in this subpart, ASM participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.705 Definitions.

For purposes of this part, the terms in this part have the same meanings as 42 CFR 512.110 and 414.1300 unless otherwise stated.

ASM beneficiary means a Medicare FFS beneficiary who is being treated by an ASM participant for a targeted chronic condition.

ASM cohort means a group of ASM participants who treat the same ASM targeted chronic condition, specifically the ASM heart failure cohort and the ASM back pain cohort.

ASM data sharing agreement means an agreement between the ASM participant, and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the ASM participant under § 512.760(e).

ASM heart failure cohort refers to all ASM heart failure participants.

ASM heart failure participant means an ASM participant who meets the ASM participant eligibility criteria related to heart failure.

ASM incentive pool means a fixed percentage of the total amount of Medicare Part B covered professional services claims paid to ASM participants with final scores within an ASM cohort during an ASM performance year that would be distributed in the form of scaled payment adjustments during an ASM payment year. CMS calculates an ASM incentive pool for each ASM cohort for each ASM payment year as described at § 512.750(c)(1)(iii).

ASM low back pain cohort refers to all ASM low back pain participants.

ASM low back pain participant means an ASM participant who meets the ASM participant eligibility criteria related to low back pain.

ASM participant means an individual clinician who, for at least one ASM performance year, satisfies the ASM participant eligibility criteria and has been selected for participation in the model as described at § 512.710(g).

ASM participant eligibility criteria means the set of criteria defined at § 512.710(b) that CMS uses to determine whether a clinician is selected to participate in ASM.

ASM payment adjustment factor means a percent value based on an ASM participant's final score as described at § 512.750(c)(1) that CMS uses in calculating adjustments to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year.

ASM payment multiplier means the numerical value equal to 1 plus the ASM payment adjustment factor determined for an ASM participant for an applicable ASM payment year as described at § 512.750(c).

ASM payment year means a calendar year in which CMS applies the ASM payment multiplier to Medicare Part B payments based on the final score achieved by that ASM participant for the ASM performance year 2 years prior.

ASM performance category means a group of applicable measures or activities used to assess ASM participant's performance on quality, cost, improvement activities, or Promoting Interoperability.

ASM performance category score means the assessment of each ASM participant's performance on the applicable measures and activities for a performance category during an ASM performance year based on the performance standards described at §§ 512.715, 512.725, 512.730, 512.735, and 512.740.

ASM performance report means the notification that CMS provides to the ASM participant for each ASM performance year, which contains the information specified at § 512.745(b).

ASM performance year means a 12-month period beginning on January 1 and ending on December 31 of each year during the first 5 calendar years of ASM test period.

ASM redistribution percentage means a percentage of Medicare Part B covered professional services payments to ASM participants during an ASM performance year that CMS distributes in the form of payment adjustment to ASM participants during an ASM payment year as described at § 512.750(c)(1)(iii).

ASM risk level means the magnitude of the maximum positive or negative net payment

adjustment percentage to which an ASM participant would be subject to during an ASM payment year as described at § 512.750(c)(1)(i).

ASM targeted chronic condition means a medical condition that is a core focus of ASM; that is, heart failure or low back pain.

ASM test period means the 7-year period from January 1, 2027, to December 31, 2033, that includes all ASM performance years and ASM payment years.

ASTP/ONC stands for the Assistant Secretary for Technology Policy/Office of the National Coordinator on Health Information Technology.

CY means calendar year.

CEHRT stands for Certified Electronic Health Records Technology that meets the requirements set forth in § 414.1305 of this chapter, except all instances of references to Merit-based Incentive Payment System (MIPS) are to be replaced with references to ASM.

Clinician has the same meaning as "eligible professional" as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination.

CMS EHR Certification ID means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health IT Product List.

Collaborative care arrangement means an arrangement that meets all of the requirements set forth in § 512.771.

Core Based Statistical Area (CBSA) means a statistical geographic area, based on the definition as identified by the Office of Management and Budget in the OMB Bulletin 23-01 issued on July 21, 2023, with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core).

Covered entity has the meaning set forth at 45 CFR 160.103.

Covered professional services means "covered services" and has the meaning set forth in § 512.110 of this chapter.

CQM stands for Clinical Quality Measures.

Days means calendar days unless otherwise specified by CMS.

Dual eligible proportion means the share of a participant's beneficiaries who are dually eligible Medicare beneficiaries

Dually eligible Medicare beneficiary means a beneficiary enrolled in both Medicare and full Medicaid benefits.

eCQM stands for electronic clinical quality measures.

EBCM stands for episode-based cost measure and means the standardized Medicare-allowed cost for the items and services furnished to a patient during an episode of care, based on FFS claims and Medicare Part D claims data.

EHR stands for Electronic Health Record and means a "Base EHR," as defined at 45 CFR 170.102.

Exchange function means the function used to translate an ASM participant's final score into an ASM payment adjustment factor as described at § 512.750(c)(1)(ii)..

Episode means all the relevant health care services a patient receives during a specified period for the treatment of a physical or behavioral health condition.

FFS stands for fee-for-service.

Final score means a composite assessment (using a scoring scale of zero to 100) for each ASM participant for an ASM performance year determined using the methodology for assessing the total performance of an ASM participant according to performance standards for applicable measures and activities for each ASM performance category as described in § 512.745.

HCC risk score stands for Hierarchical Condition Category risk score and means the risk score assigned to a Medicare beneficiary in accordance with the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act.

Health-related social need means an unmet, adverse social condition that can contribute to poor health outcomes and is a result of underlying social determinants of health, which refer to the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Improvement activities mean activities relating to care coordination, integration of specialty and

primary care, and addressing health-related social needs of patients.

Mandatory geographic area means a CBSA or metropolitan division as defined by the Office of Management and Budget and selected by CMS under the terms of § 512.710(f).

Meaningful EHR user means an ASM participant who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability ASM performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.

Measure achievement points mean numerical values assigned to an ASM participant's reported performance data, that CMS uses to calculate an ASM performance category score.

Metropolitan division means--(1) A county or group of counties (or equivalent entities) delineated within a larger metropolitan statistical area, provided that the larger metropolitan statistical area contains a single core with a population of at least 2.5 million and other criteria are met; and

(2) Consists of one or more main or secondary counties that represent an employment center or centers, plus adjacent counties associated with the main/secondary county or counties through commuting ties.

Metropolitan statistical area means the county or counties (or equivalent entities) associated with at least one urban area of at least 50,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties.

MIPS stands for the Merit-based Incentive Payment System.

NPI stands for National Provider Identifier.

ONC-ACB stands for ONC-Authorized Certification Bodies.

Physician has the meaning set forth in section 1861(r) of the Act.

Primary care services has the meaning set forth in section 1842(i)(4) of the Act.

Risk indicator refers to hierarchical condition category (HCC) risk scores under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act or the proportion of beneficiaries with dual eligible status used in calculating the complex patient scoring adjustment as

defined at § 512.745(a)(3).

SAFER stands for Safety Assurance Factors for EHR Resilience.

Scaling factor means a numerical value calculated by CMS to ensure that the total estimated payment adjustments in an ASM payment year are equal to the ASM incentive pool for the applicable ASM payment year as described at § 512.750(c)(1)(iv).

Small practice means a practice consisting of 15 or fewer clinicians at the time we identify ASM participants for an ASM performance year as described at § 512.710(g).

Specialty type means a medical specialty as determined by the specialty code indicated on the plurality of a clinician's Medicare Part B claims.

Solo practitioner means a practice consisting of 1 clinician at the time we identify ASM participants for an ASM performance year as described at § 512.710(g).

Submission type means the mechanism by which the ASM submitter submits data to CMS in the form and manner specified by CMS, including, but not limited to all of the following:

(1) Direct.

(2) Log in and upload.

(3) Log in and attest.

Third -party intermediary has the meaning set forth in § 414.1305 of this chapter.

TIN stands for Taxpayer Identification Number.

Topped out measure has the meaning of either topped out process measure or topped out non-process measure set forth in § 414.1305 of this chapter.

U.S. Territories has the meaning set forth in § 512.110 of this chapter.

§ 512.710 Participant eligibility and selection.

(a) *Mandatory ASM participation.*

(1) Unless otherwise specified, any clinician who meets all ASM participant eligibility criteria as specified in paragraph (b) of this section and furnishes covered services during any applicable ASM performance year within the ASM test period is considered an ASM participant for the duration of the model.

(i) 2027 ASM performance year: ASM participants—

(A) Are measured for performance and exempted from MIPS participation, if applicable, during CY 2027;

(B) Report and are scored during CY 2028; and

(C) Receive payment adjustments for CY 2027 performance in CY 2029.

(ii) 2028 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2028 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2028;

(B) Report and are scored during CY 2029; and

(C) Receive payment adjustments for CY 2028 performance in CY 2030.

(iii) 2029 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2029 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2029;

(B) Report and are scored during CY 2030; and

(C) Receive payment adjustments for CY 2029 performance in CY 2031.

(iv) 2030 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2030 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2030;

(B) Report and are scored during CY 2031; and

(C) Receive payment adjustments for CY 2030 performance in CY 2032.

(v) 2031 ASM performance year: ASM participants—

(A) Meeting ASM eligibility criteria for the 2031 performance year are measured for performance and exempted from MIPS participation, if applicable, during CY 2031;

(B) Report and are scored during CY 2032; and

(C) Receive payment adjustments for CY 2031 performance in CY 2033.

(2)(i) For any ASM performance year within the ASM test period that an ASM participant does not meet the criteria for mandatory participation set forth in this section, the ASM participant is not subject, for the applicable ASM performance year, to §§ 512.715, 512.720, 512.745, and 512.750.

(ii) For a ASM performance year described in paragraph (a)(2)(i) of this section, the ASM

participant is no longer eligible for the waivers as described at § 512.775 and is instead subject to MIPS reporting obligations, if applicable.

(b) *ASM participant eligibility criteria.* CMS uses the following set of criteria to determine whether a clinician is an ASM participant:

(1) Is a clinician who bills claims under the Medicare Physician Fee Schedule.

(2) Is identified by TIN/NPI as a selected specialty type as described in paragraph (d) of this section.

(3) Meets the EBCM episode volume threshold applicable to an ASM targeted chronic condition as described at paragraph (e) of this section.

(4) Is located in one of the mandatory geographic areas selected in accordance with paragraph (f) of this section.

(c) *Participant exclusion due to change in TIN during an ASM performance year.*

(1) An ASM participant who stops assigning billing rights to the TIN used to identify the ASM participant and begins assigning billing rights to a new TIN during an applicable ASM performance year must notify CMS of the change in a form and manner determined by CMS within 30 days of the change.

(2)(i) An ASM participant who notifies CMS of a change in TIN during an ASM performance year is not subject, for the applicable ASM performance year, to §§ 512.715, 512.720, 512.745, and 512.750.

(ii) The ASM participant described in paragraph (c)(2)(i) of this section is no longer eligible for the waivers as described at § 512.775 and is instead subject to MIPS reporting obligations, if applicable.

(d) *Specialty type.* ASM participants have one of the following Medicare Part B specialty codes indicated on the plurality of their Medicare Part B claims:

(1) Heart failure specialty type ¾

(i) Cardiology.

(ii) [Reserved]

(2) Low back pain specialty type ¾

(i) Anesthesiology.

(ii) Interventional Pain Management.

(iii) Neurosurgery.

(iv) Orthopedic Surgery.

(v) Pain Management.

(vi) Physical Medicine and Rehabilitation.

(e) *EBCM episode volume.* To determine if a clinician meets the ASM participant eligibility criterion defined in paragraph (b)(3) of this section, CMS uses the volume of EBCM episodes related to ASM targeted chronic conditions that are attributed to a clinician using the applicable EBCM specifications and attribution methodology.

(1) *Heart failure EBCM.* Clinicians who have a specialty designation type described at § 512.710(d)(1) and 20 or more heart failure EBCM episodes attributed in accordance with the heart failure episode-based cost measure as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year meet the ASM participant eligibility criterion defined in paragraph (b)(3) of this section.

(2) *Low back pain EBCM*. Clinicians who have a specialty designation type described at § 512.710(d)(2) and 20 or more low back pain EBCM episodes attributed in accordance with the low back pain episode-based cost measure as specified under MIPS during the calendar year 2 years prior to the applicable ASM performance year meet the ASM participant eligibility criterion defined in paragraph (b)(3) of this section.

(f) *Mandatory geographic areas.* CMS uses a stratified random sampling methodology described in paragraphs (f)(2) and (f)(3) of this section to select CBSA and metropolitan divisions (in cases where OMB divides large metropolitan statistical areas into metropolitan divisions) from which CMS identifies clinicians for participation in ASM.

(1) *Exclusions.* CMS excludes from the selection of CBSAs and metropolitan divisions applicable areas that meet any of criteria described in paragraph (f)(1)(i) or (f)(2)(ii) of this section.

(i) Areas that do not meet the criteria described in paragraphs (f)(1)(i)(A) and (f)(1)(i)(B) of this section:

(A) Have at least one clinician with a specialty designation type described at § 512.710(d)(1) with 20 or more heart failure EBCM episodes attributed between January 1, 2024 and December 31, 2024.

(B) Have at least one clinician with a specialty designation type described at § 512.710(d)(2) with 20 or more low back pain EBCM episodes attributed between January 1, 2024 and December 31, 2024.

(ii) Areas located entirely in U.S. Territories.

(2) *CBSA and metropolitan division stratification process.* Prior to sampling CBSAs and metropolitan divisions, CMS stratifies CBSAs and metropolitan divisions, excluding those described in paragraph (f)(1) of this section, into six mutually exclusive strata based on three CBSA/metropolitan division-level characteristics (average total Part A and Part B episode spending, volume of eligible episodes, and metropolitan division status) as described in paragraphs (f)(2)(i) through (vi) of this section. "Average total episode spending" as the term is used in paragraphs (f)(2)(i) through (vi) of this section, is measured using the average total Part A and Part B episode spending using claims data from January 1, 2024 to December 31, 2024 relating to heart failure and low back pain episodes, as specified under the episode-based cost measures described in § 512.710(e). Values below the median are characterized as "Low" average total episode spending. Values at or above the median are characterized as "High" average total spending. "Eligible episode volume" as the term is used in paragraphs (f)(2)(i) through (vi) of this section, is measured as the total count of eligible heart failure and low back pain episodes, as specified under the episode-based cost measures described in § 512.710(e), in a CBSA between January 1, 2024 and December 31, 2024. CMS categorizes CBSAs with values below the median as "Low;" CBSAs at-or-above the median and below the 95th percentile as "High;" and CBSAs at-or-above the 95th percentile as "Very High.".

(i) CBSAs with "Low" average total episode spending and "Low" eligible episode volume.

(ii) CBSAs with "Low" average total episode spending and "High" eligible episode volume.

(iii) CBSAs with "High" average total episode spending (as defined below) and "Low" eligible episode volume.

(iv) Eligible CBSAs with "High" average total episode spending and "High" eligible episode volume.

(v) Eligible CBSAs with "Very High" eligible episode volume.

(vi) Eligible metropolitan divisions.

(3) *Sampling of CBSAs and metropolitan divisions.* CMS selects approximately 40 percent of

CBSAs and metropolitan divisions from each stratum to select the mandatory geographic areas. If 40 percent of a given stratum does not result in a whole number of CBSAs or metropolitan divisions, CMS rounds up to the next whole number to ensure that at least 40 percent of areas from each stratum are selected.

(4) *Assignment of CBSA or metropolitan division code to clinicians.* CMS assigns a CBSA or a metropolitan division code to every TIN/NPI with attributed EBCM episodes related to ASM targeted chronic conditions for the applicable calendar year as described in paragraph (e) of this section to determine ASM participation eligibility for an applicable ASM performance year:

(i) CMS assigns each attributed EBCM episode a ZIP Code, which represents the service location where the attributed TIN/NPI encounters the beneficiary attributed to the episode the most, based on the plurality of Part B claims used to construct the episode. If the ZIP Codes representing service location where the attributed TIN/NPI appears in equal number in the Part B claims used to construct the episode, then CMS assigns the ZIP Code based on the ZIP Code that represents the Part B claim with--

(A) The highest total cost indicated by the total standardized allowed amount; or

(B) Most recent date.

(ii) CMS assigns each attributed EBCM episode a CBSA or metropolitan division code based on the ZIP Code assigned to the episode as described in paragraph (f)(4)(i) of this section. If the ZIP Code assigned to the EBCM episode is in multiple CBSAs or metropolitan divisions, then CMS assigns the EBCM episode the CBSA or metropolitan division code where the ZIP Code has the highest proportion of --

(A) Total addresses; or

(B) Business addresses.

(iii) CMS assigns each TIN/NPI combination a single CBSA or metropolitan division code based on the most common CBSA or metropolitan division code assigned to episodes attributed to the TIN/NPI as described in paragraph (f)(4)(ii) of this section. If the TIN/NPI has equal number of episodes across multiple CBSAs or metropolitan divisions, then CMS assigns the TIN/NPI a CBSA or metropolitan division with the CBSA or metropolitan division that has either of the following:

(A) The highest total risk-adjusted episode spending across all episodes assigned to the CBSA or

metropolitan division.

(B) Episodes with more recent dates.

(g) *Selection and notification process for ASM participants*. For each ASM performance year, CMS identifies all clinicians furnishing covered services using the ASM participant eligibility criteria specified in paragraph (b) of this section and applicable data from 2 calendar years prior to each ASM performance year. Any clinician selected for participation for any year of the model is considered an ASM participant for the remainder of the ASM test period.

(1) *2027 ASM performance year only—*

(i) *Preliminarily eligible ASM participants.* Using applicable data from calendar year 2024, CMS identifies all clinicians who meet the ASM participant eligibility criteria for participation starting in the 2027 ASM performance year/2029 ASM payment year. The clinicians identified as preliminarily eligible ASM participants are made public in a form and manner determined by CMS.

(ii) *Final ASM participants.* CMS identifies the final ASM participants selected for participation starting in the 2027 ASM performance year/2029 ASM payment year by confirming that the preliminarily eligible ASM participants identified under paragraph (g)(1)(i) of this section meet the ASM participant eligibility criteria using applicable data from CY 2025. The clinicians selected as ASM participants starting the 2027 ASM performance year/2029 ASM payment year is made public in a form and manner determined by CMS.

(2) *2028 ASM performance year and subsequent years.*

(i) Beginning with the 2028 ASM performance year/2030 ASM payment year, CMS determines if the previously selected ASM participants continue to meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. An ASM participant who does not meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year is not subject to provisions described at §§ 512.715, 512.720, and 512.745 and must, if applicable, participate in MIPS. The final ASM participants selected for participation for each applicable ASM performance year is made public in a form and manner determined by CMS.

(ii) Beginning with the 2028 ASM performance year/2030 ASM payment year and prior to the

start of each ASM performance year, CMS determines if additional clinicians not previously identified as ASM participants meet the ASM participant eligibility criteria for the upcoming ASM performance year/ASM payment year using applicable data from the calendar year 2 years prior to the applicable ASM performance year. The final ASM participants selected for participation for each applicable ASM performance year is made public in a form and manner determined by CMS.

§ 512.715 Overview of performance assessment.

(a) *General.* As further described in §§ 512.725, 512.730, 512.735, and 512.740:

(1) An ASM participant receives a specific number of points for its performance on each measure or activity within an ASM performance category.

(2) CMS assigns the total amount of points an ASM participant may receive for its performance on a measure or activity.

(3) CMS calculates a final score as described at § 512.745 using the points received across all four ASM performance categories.

(b) *Data sources.*

(1) CMS uses Medicare claims data and Medicare administrative data reported to calculate measure scores included in the quality and cost ASM performance categories under §§ 512.725 and 512.730.

(2) CMS uses model-specific data reported under § 512.720 to calculate applicable measure or activity scores for the quality, improvement activities, and Promoting Interoperability ASM performance categories under §§ 512.725, 512.735, and 512.740.

§ 512.720 Data submission requirements.

(a) *Applicable performance categories and data submission requirements.*

(1) Except as provided in paragraph (a)(2) of this section, as applicable, ASM participants must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability ASM performance categories described in §§ 512.725(b) and (c), 512.735(b), and 512.740 in accordance with this section. The data may also be submitted on behalf of the ASM participant by a third-party intermediary.

(i) For the quality ASM performance category, a data submission must—

(A) Include numerator and denominator data for at least one applicable quality measure described in § 512.725(b) or (c) that is not an administrative claims-based collection type and meets the data completeness requirement as specified at § 512.725(f) and

(B) Be submitted at the TIN/NPI level, unless the ASM participant is excepted under paragraph (f) of this section.

(ii) For the improvement activities ASM performance category, a data submission must—

(A) Include an attestation of meeting the specifications of each required improvement activity described in § 512.735(c); and

(B) Be submitted at the TIN level;

(iii) For the Promoting Interoperability ASM performance category, a data submission must do all of the following:

(A) Include all of the following elements:

(*1*) Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS at § 512.740(b).

(*2*) Required attestation statements, as specified by CMS at § 512.740(b).

(*3*) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL).

(*4*) The start date and end date for the applicable performance period as set forth in § 512.740(a).

(B) Be submitted at the TIN level.

(2) There are no data submission requirements for the cost ASM performance category measures and activities described under § 512.730(b) or administrative claims-based quality measures as described in § 512.725(b) or (c). Performance in the cost ASM performance category and administrative claims-based quality measures are calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(b) *Data submission types for ASM participants.* An ASM participant must submit their data using the following:

(1) For the quality ASM performance category, the direct and login and upload submission types.

(2) For the improvement activities and Promoting Interoperability ASM performance categories,

the direct, login and upload, or login and attest submission types.

(c) *Use of multiple data submission types.* ASM participants may submit their data using multiple data submission types for any ASM performance category described in paragraph (a)(1) of this section provided that the ASM participant uses the same identifier for all ASM performance categories and all data submissions.

(d) *Data submission deadlines*. The data submission deadline is March 31st of the calendar year following the close of the applicable ASM performance year or a later date as specified by CMS for the direct, login and upload, and login and attest submission types.

(e) *Treatment of multiple data submissions.*

(1)(i) For multiple data submissions received in the quality and improvement activities ASM performance categories in accordance with paragraphs (a)(1)(i) and (ii) of this section for an individual ASM participant from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS calculates and scores each submission received and assign the highest of the scores.

(ii) For multiple data submissions received for an individual ASM participant from one or multiple submitters in the same organization, CMS scores the most recent submission.

(2) For multiple data submissions received for the Promoting Interoperability ASM performance category in accordance with paragraph (a)(1)(iii) of this section, CMS calculates a score for each data submission received and assigns the highest of the scores.

(f) *Small practice quality measures submission.* ASM participants who are part of a small practice may report quality measures in the quality ASM performance category at the TIN level.

§ 512.725 Quality ASM performance category.

(a) *ASM performance year for quality measures.* Beginning with 2029 ASM payment year, the ASM performance year for quality measures is the full calendar year from January 1 to December 31 that occurred 2 years prior to the applicable ASM payment year, except as otherwise specified for administrative claims-based measures.

(b) *Quality measures for ASM heart failure cohort.* CMS uses the following quality measures, as specified by CMS for the MIPS quality performance category unless otherwise stated, to assess

performance for ASM heart failure participants in the quality ASM performance category:

(1) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (MIPS Q492).

(2) Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q008).

(3) Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (MIPS Q005).

(4) Controlling High Blood Pressure (MIPS Q236)

(5) Functional Status Assessments for Heart Failure (MIPS Q377).

(c) *Quality measures for ASM low back pain cohort*. CMS uses the following quality measures, as specified by CMS for the MIPS quality performance category unless otherwise stated, to assess performance for ASM low back pain participants in the quality ASM performance category:

(1) Use of High-Risk Medications in Older Adults (MIPS Q238).

(2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan (MIPS Q134).

(3) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (MIPS Q128).

(4) Functional Status Change for Patients with Low Back Impairments (MIPS Q220).

(d) *Removal, addition, and maintenance of technical specifications of quality measures.* CMS uses notice-and-comment rulemaking to communicate any updates or changes to the quality measure sets described in paragraphs (b) and (c) of this section.

(e) *Data submission criteria for the quality ASM performance category.*

(1) CMS uses quality measures as described in paragraphs (b) and (c) of this section with the following data collection types:

(i) MIPS CQMs.

(ii) eCQMs.

(iii) Administrative claims-based.

(2) *Data submission requirements.*

(i) An ASM heart failure participant must submit data on all quality measures specified in paragraph (b) of this section using MIPS CQMs or eCQMs.

(ii) An ASM low back pain participant must submit data on all quality measures specified in paragraph (c) of this section using MIPS CQMs or eCQMs, unless otherwise stated.

(iii) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(3*)* An ASM participant is not required to submit data for the calculation of administrative claims-based measures so long as data submission requirements as specified at § 512.720(a)(1)(i) are met.

(f) *Data completeness requirement for the quality ASM performance category.*

(1) Except as specified at paragraph (e)(3) of this section and for each required measure specified in paragraphs (b) or (c) of this section, ASM participants must submit data on at least 75 percent of the ASM participant's patients that meet the measure's denominator criteria, regardless of payer.

(2) ASM participants receive zero measure achievement points for each measure required in paragraphs (b) or (c) of this section that does not meet the data completeness requirement, as specified at paragraph (f)(1) of this section.

(3) CMS excludes from an ASM's participant total measure achievement points and total available measure achievement points any measures required under paragraphs (b) or (c) of this section that meet the respective measure's data completeness requirement, but do not have a benchmark.

(g) *Minimum case requirements.*

(1) Unless otherwise specified by CMS, the minimum case requirement for each quality measure required in paragraphs (b) or (c) of this section is 20 cases.

(2) CMS excludes from an ASM's participant total measure achievement points and total available measure achievement points any measures required under paragraphs (b) or (c) of this section that meet the respective measure's data completeness requirement as specified at paragraph (f)(1) of this section but do not meet the measure's case minimum requirement as specified at paragraph (g)(1) of this section.

(h) *Quality measure achievement points and quality ASM performance category scoring.* Unless a different scoring weight is assigned by CMS, performance in the quality ASM performance category

comprises of 50 percent of a ASM participant's final score for each ASM payment year.

(1) *Measure achievement points.*

(i) For each ASM performance year, ASM participants receive between 1 and 10 measure achievement points (including partial points) for each required measure as specified in paragraphs (b) or (c) of this section on which data is submitted in accordance with paragraph (e) of this section that does all of the following:

(A) Has a benchmark specified in paragraph (h)(2) of this section.

(B) Meets the case minimum requirements specified in paragraph (g) of this section.

(C) Meets the data completeness criteria specified in paragraph (f) of this section.

(D) For each administrative claims-based measure with a benchmark as described at paragraph (h)(2)(iii) of this section and meets the case minimum requirement at paragraph (g) of this section.

(ii) The number of ASM measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution.

(iii) ASM participants receive zero ASM measure achievement points for each measure required in paragraphs (b) or (c) of this section on which no data is submitted in accordance with § 512.720.

(iv) ASM participants who submit data in accordance with paragraphs (e) through (g) of this section on a single required measure via multiple applicable collection types are scored only on the data submission with the greatest number of measure achievement points.

(2)(i) *Benchmarks.* Except as provided in paragraph (h)(2)(iii) of this section, CMS bases benchmarks on an ASM participant's performance by collection type, from one following data sources:

(A) Reported by ASM participants, to the extent feasible, during the ASM performance year.

(B) A previous ASM performance year, if available.

(C) Another period determined by CMS.

(ii) Each benchmark must have a minimum of 20 ASM participants who reported the measure having met the following criteria:

(A) The case minimum requirements in paragraph (g) of this section.

(B) The data completeness requirement as specified in paragraph (f) of this section.

(C) A performance rate that is greater than zero.

(iii) CMS calculates a benchmark for an administrative claims quality measure using the performance on the measure during the current ASM performance year.

(iv) CMS determines a benchmark using decile categories based on the applicable period of data used to determine the measure's benchmark.

(3) *Topped out measures.* CMS identifies topped out measures in the benchmarks for each ASM performance year based on within-model performance on each measure.

(4) *Calculation of the quality ASM performance category score.*

(i) Unless otherwise specified by CMS, an ASM participant's quality ASM performance category score is the sum of all measure achievement points assigned for the applicable measures for the quality ASM performance category.

(A) The sum is divided by the total available measure achievement points.

(B) The quality ASM performance category score cannot exceed 100 percentage points.

(ii) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 512.720(d), performance is based on data for 9 consecutive months of the applicable ASM performance year.

(A) Significant changes or errors means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to the following:

(1) Changes to codes (such as ICD-10, CPT, or HCPCS codes) or the active status of codes.

(2) The inadvertent omission of codes or inclusion of inactive or inaccurate codes.

(3) Changes to clinical guidelines or measure specifications.

(B) CMS publishes a list of all measures scored in a form and manner specified by CMS.

(C) If the data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from an ASM participant's total measure achievement points and total available measure achievement points.

(iii) An ASM participant does not receive a quality ASM performance category score if the ASM participant meets the quality ASM performance category data submission requirements specified at § 512.720(a)(1)(i) but does not meet the case minimum requirements specified in paragraph (g) of this

section for any required quality ASM performance category measure specified in paragraphs (b) or (c) of this section, as applicable, that has a benchmark as specified in paragraph (h)(2) of this section.

§ 512.730 Cost ASM performance category.

(a) *ASM performance year for cost performance measures.* Beginning with the 2029 ASM payment year, the ASM performance year for cost measures is the full calendar year from January 1 to December 31 that occurred 2 years prior to the applicable ASM payment year.

(b) *Cost measures.* For purposes of assessing performance of ASM participants on the cost ASM performance category, CMS—

(1) For ASM heart failure participants, assess and score the participants on the Heart Failure EBCM (COST_HF_1), as specified under MIPS.

(2) For ASM low back pain participants, assess and score the participants on the Low Back Pain EBCM (COST_LBP_1), as specified under MIPS.

(c) *Adding or removing* cost *measures.* CMS may add new cost measures to, or remove existing cost measures from, the cost ASM performance category through notice and comment rulemaking.

(d) Minimum case requirements. Unless otherwise specified by CMS, the minimum case requirement for each cost measure is 20 cases.

(1) Each cost measure is attributed at the TIN/NPI level according to the measure specification for the applicable ASM performance year.

(2) An ASM participant must meet the minimum case volume to be scored on a cost measure.

(e) *Cost measure achievement points and cost ASM performance category scoring.* Unless a different scoring weight is assigned by CMS, performance in the cost ASM performance category comprises 50 percent of an ASM participant's final score for each ASM performance year.

(1) *ASM measure achievement points.* (i) For each cost measure attributed to an ASM participant, the ASM participant receives one to ten achievement points (including partial points) based on the ASM participant's performance on the cost measure during the ASM performance year compared to the cost measure's benchmark.

(i) Achievement points are awarded based on which benchmark range the ASM participant's performance on the measure is in.

(2) *Benchmarks*

(i) CMS bases cost measure benchmarks on cost measure performance during the ASM performance year.

(A) Each benchmark must have a minimum of 20 ASM participants who meet the minimum case volume specified in paragraph (d) of this section for CMS to determine a benchmark for the cost measure.

(B) If a benchmark is not determined for a cost measure, then the measure is not scored.

(ii) CMS determines 10 benchmark ranges based on the median cost of all ASM participants attributed the measure, plus or minus standard deviations. CMS awards achievement points based on which benchmark range an ASM participant's measure score corresponds.

(3) *Calculation of the cost ASM performance category score.* Except as otherwise specified in paragraph (e)(3)(i) of this section, the cost ASM performance category score is the sum of the total number of achievement points earned by the ASM participant divided by the total number of available achievement points, not to exceed 100 percent.

(i) An ASM participant does not receive a cost ASM performance category score if the ASM participant is not attributed the required cost measure for the ASM performance year specified in paragraph (b) of this section because the ASM participant has not met the case minimum specified in paragraph (d) of this section for the required cost measure or if a benchmark has not been created for a required cost measure as specified in paragraph (e)(2) of this section.

(ii) If data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the ASM performance year, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the ASM participant's cost ASM performance category score and a cost ASM performance category score is not calculated.

(A) Significant changes or errors means changes to or errors in a measure that are outside the control of the clinician and its agents, and that CMS determines may result in patient harm or misleading results.

(B) Significant changes or errors include, but are not limited to, changes to codes (such as ICD-10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications.

(C) CMS empirically assesses the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

§ 512.735 Improvement activities ASM performance category.

(a) *ASM performance year for improvement activities.* Beginning with the 2029 ASM payment year, the ASM performance year for improvement activities is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

(b) *Improvement activities.* CMS uses the improvement activities specified in paragraph (c) of this section to evaluate performance of ASM participants in the improvement activities ASM performance category.

(c) *Improvement activities specifications.*

(1) *Improvement Activity 1 (IA-1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening.* An ASM participant must have evidence of processes, workflows, or technology that require the ASM participant to do all of the following:

(i) Confirm the ASM beneficiary has access to primary care services and, if not, assist the ASM beneficiary in finding a clinician who provides primary care services.

(ii) Communicate relevant information back to the ASM beneficiary's primary care provider following the ASM beneficiary's visit with the ASM participant.

(iii) Determine whether the ASM beneficiary has received an annual health-related social needs screening in the primary care setting and, if not, encourage the primary care services provider to conduct the screening or allow the ASM participant to conduct the health-related social needs screening.

(2) *Improvement Activity 2 (IA-2): Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements*. An ASM participant must do all of the following:

(i) Have at least one executed collaborative care arrangement between a primary care practice with which the ASM participant shares ASM beneficiaries.

(ii) The collaborative care arrangement must include collaborative efforts related to at least three of the following five elements:

(A) Data sharing, which includes setting expectations for bi-directional sharing of patient information between the parties to the collaborative care arrangement, including but not limited to test results, treatment plans, and follow-up recommendations.

(B) Co-management, which includes defining co-management approaches, where the parties to the collaborative care arrangement work together to furnish complementary care for patients with complex or chronic conditions.

(C) Transitions in care planning, which includes defining protocols for seamless transitions of care between ASM participants, the primary care practice, or different care settings.

(D) Closed-loop communication, such as clearly articulated processes enforcing parameters on how ASM beneficiaries may be referred between the parties to the collaborative care arrangement.

(E) Care coordination integration comprised of structured processes to embed care coordination processes into the ASM participant's practice workflow.

(d) *Scoring for improvement activities ASM performance category.*

(1) *ASM measure achievement points.* ASM participants receive 10 ASM measure achievement points for attesting "yes" for each improvement activity specified in paragraph (c) in compliance with the data submission requirements at § 512.720.

(2) *Calculation of the improvement activities ASM performance category score.* Unless otherwise specified by CMS, CMS sums the total achievement points for all submitted improvement activities and divides this sum by the total number of available achievement points for the required improvement activities as specified in paragraph (c) of this section, not to exceed 100 percent.

§ 512.740 Promoting Interoperability ASM performance category.

(a) *ASM performance year for the Promoting Interoperability ASM performance category.* Beginning with the 2029 ASM payment year, the ASM performance year for Promoting Interoperability measures is the minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable ASM payment year, up to and including the full calendar year.

(b) *Reporting for the Promoting Interoperability ASM performance category.* To earn an ASM

performance category score greater than zero for the Promoting Interoperability ASM performance category for inclusion in the final score, an ASM participant must be a meaningful EHR user and meet the following criteria:

(1) *CEHRT.* Use CEHRT as defined at § 414.1305 for the ASM performance year.

(2) *ASM Promoting Interoperability objectives and measures.* Report on the following MIPS Promoting Interoperability measures, as specified by CMS through rulemaking:

(i) An ASM Participant must report both of the following measures or claim an exclusion or exclusions to fulfill the e-Prescribing objective:

(A) e-Prescribing (Measure ID #: PI_EP_1).

(B) Query of PDMP (Measure ID # PI_EP_2).

(ii) An ASM Participant must fulfill the Health Information Exchange objective through one of the following three options:

(A) Report the Support Electronic Referral Loops by Sending Health Information (Measure ID # PI_HIE_1) and Support Electronic Referral Loops by Receiving and Reconciling Health Information (Measure ID # PI_HIE_4).

(B) Health Information Exchange (HIE) Bi-Directional Exchange (Measure ID # PI_HIE_5).

(C) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) (Measure ID # PI_HIE_6).

(iii) An ASM Participant must fulfill the Provider to Patient Exchange objective by reporting the Provide Patients Electronic Access to Their Health Information measure (Measure ID # PI_PEA_1).

(iv) An ASM Participant must fulfill the Public Health and Clinical Data Exchange objective by reporting both measures:

(A) Immunization Registry Reporting (Measure ID # PI_PHCDDR_1).

(B) Electronic Case Reporting (Measure ID PI_PHCDRR_3).

(3) *Reporting ASM Promoting Interoperability objectives and measures*. Comply with the following reporting requirements:

(i) For each measure under paragraph (b)(2) of this section, report—

(A) The numerator (of at least one) and denominator;

(B) Yes/no statement; or

(C) An exclusion that includes an option for the exclusion.

(ii) Report that the ASM participant completed the actions included in the MIPS Promoting Interoperability Security Risk Analysis measure (Measure ID # PI_PPHI_1) within the calendar year of the ASM performance year.

(iii) Submit an affirmative attestation regarding the ASM participant's completion of the annual self-assessment checklist under the MIPS Promoting Interoperability High Priority Practices Guide of the SAFER Guides measure (Measure ID # PI_PPHI_2) within the calendar year of the ASM performance year.

(4) *Supporting use of CEHRT.* ASM participants must support the use of CEHRT by fulfilling the following requirements:

(i) *Supporting the use and performance of CEHRT.* To fulfill ASM requirements to engage in activities related to supporting clinicians with the performance of CEHRT, the ASM participant:

(A) Must attest by providing all of the following:

(*1*) Acknowledgement of the requirement to cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received.

(*2*) If requested, cooperation in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that the technology meets, or can be used to meet, the definition of CEHRT, including by permitting timely access to the technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

(B) May attest to the following objectives and measures:

(*1*) Acknowledgement of the option to cooperate in good faith with ONC-ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC-ACB surveillance is received.

(*2*) If requested, cooperation in good faith with ONC-ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by

45 CFR part 170, subpart E, to the extent that the technology meet, or can be used to meet, the definition of CEHRT, including by permitting timely access to the technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

(ii) Actions to limit or restrict the compatibility or interoperability of CEHRT. To fulfill ASM requirements for activities related to limiting or restricting the compatibility or interoperability of CEHRT, the ASM participant must not knowingly and willfully take action, such as to disabling functionality, to limit or restrict the compatibility or interoperability of CEHRT.

(c) *Scoring the Promoting Interoperability ASM performance category.*

(1) *ASM measure achievement points.*

(i) An ASM participant earns a score for each measure by fulfilling the reporting requirements specified at paragraph (b) of this section. Score amounts are set forth in the MIPS measure specifications.

(ii) If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure as set forth in the MIPS measure specifications.

(2) *Promoting Interoperability ASM performance category score*. Unless otherwise specified by CMS, CMS sums the scores for each of the required measures and divides this sum by the total number of available Promoting Interoperability points. The Promoting Interoperability ASM performance category score cannot exceed 100 percent.

§ 512.745 Final scoring.

(a) *Final score calculation.* CMS calculates a final score of zero to 100 points using the formula specified at paragraph (a)(5) of this section for each ASM participant that meets the requirements to receive a final score as specified in paragraph (a)(2) of this section.

(1) *ASM performance category weights and scoring adjustments.* CMS calculates the final score using the ASM performance category weights and scoring adjustments as follows:

(i) Quality ASM performance category weight is 50 percent.

(ii) Cost ASM performance category weight is 50 percent.

(iii) The improvement activities ASM performance category has a scoring adjustment that is applied to the final score without weighting.

(A) ASM participants that achieve a 100 percent score for the improvement activities ASM

performance category do not receive an improvement activities ASM performance category scoring adjustment to final score.

(B) ASM participants that receive a 50 percent improvement activities ASM performance category score receive an improvement activities ASM performance category scoring adjustment of negative 10 points to the final score.

(C) ASM participants that receive a zero percent improvement activities ASM performance category score receive an improvement activities ASM performance category scoring adjustment of negative 20 points to the final score.

(iv) The Promoting Interoperability ASM performance category has a scoring adjustment that is applied to the final score without weighting.

(A) To determine the Promoting Interoperability ASM performance category scoring adjustment as described in paragraph (a)(1)(iv) of this section, the Promoting Interoperability ASM performance category score is multiplied by 100, the product is then subtracted from 100 and divided by the maximum negative Promoting Interoperability ASM performance category scoring adjustment of 10 points.

(B) The maximum Promoting Interoperability ASM performance category scoring adjustment is negative 10 points.

(2) *Requirements to receive a final score.* Except as described at § 512.780(c)(1), CMS determines whether an ASM participant receives a final score for the applicable ASM performance year depending on the data submitted by the ASM participant.

(i) Except as described in paragraph (a)(2)(iii) of this section, CMS calculates a final score greater than zero but not exceeding 100 as described in paragraph (a) of this section for the applicable ASM performance year for all ASM participants that meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(ii) CMS assigns a final score of zero for the applicable ASM performance year to all ASM participants who do not meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(iii) CMS does not assign a final score for the applicable ASM performance year to ASM participants who do all of the following:

(A) Meet the quality ASM performance category data submission requirements as specified at § 512.720(a)(1)(i).

(B)(*1*) Do not receive a quality ASM performance category score under § 512.725(h)(4)(iii); or

(*2*) Do not receive a cost ASM performance category score under § 512.730(e)(3)(i).

(3) *Complex patient scoring adjustment.* CMS adds a complex patient scoring adjustment to the final score for the ASM performance year, if applicable, if an ASM participant meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section and the criteria defined in paragraph (a)(3)(i) of this section for the applicable ASM performance year.

(i) The complex patient scoring adjustment is limited to ASM participants with a risk indicator at or above the risk indicator calculated median for their ASM cohort. To determine the median for the respective risk indicator (HCC and dual eligible proportion) for each ASM cohort, risk indicators associated to an ASM participant in the corresponding ASM cohort from the calendar year preceding the applicable ASM performance year, for all ASM participants within an ASM cohort who meet the data submission requirements for the quality ASM performance category at § 512.725(a)(1)(i) are used.

(ii) Beginning with the 2027 ASM performance year, for ASM participants, the complex patient scoring adjustment components are calculated as follows for the specific risk indicators:

(A) Medical complex patient scoring adjustment component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS in accordance with section 1853(a)(1) of the Act) seen by the ASM participant.

(B) Social complex patient scoring adjustment component = 1.5 + 4 * associated dual proportion standardized score.

(C) The components specified in paragraphs (a)(3)(ii)(A) and (B) of this section are added together to calculate one overall complex patient scoring adjustment. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score−risk indicator mean)/risk indicator standard deviation.

(iii) The complex patient scoring adjustment cannot exceed 10 and cannot be below zero.

(4) *Small practice scoring adjustment.*

(i) *Scoring adjustment for an ASM participant that is in a small practice and is not a solo practitioner*. CMS add 10 points to the final score of an ASM participant that meets all of the following:

(1) Is in a small practice.

(2) Is not a solo practitioner.

(3) Meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(ii) *Scoring adjustment for ASM participant that is a solo practitioner.* CMS adds 15 points to the final score of an ASM participant that is a solo practitioner and meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(5) *Final score formula.* Final score = [quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + complex patient scoring adjustment + small practice scoring adjustment. The final score cannot be below zero points or exceed 100 points.

(b) *ASM performance report.* For each ASM performance year, CMS provides each ASM participant with an ASM performance report, in a form and manner determined by CMS, containing all of the following:

(1) The ASM participant's score for each ASM performance category.

(2) The ASM participant's complex patient scoring adjustment under paragraph (a)(3) of this section, as applicable.

(3) The ASM participant's small practice or solo practitioner scoring adjustment under paragraph (a)(4) of this section, as applicable.

(4) The ASM participant's final score, as applicable.

(5) The ASM payment adjustment factor under § 512.750(c)(1).

(6) The ASM payment multiplier under § 512.750(c).

§ 512.750 Payment adjustment.

(a) *General*. Except as described in paragraph (f) of this section, for covered professional services furnished by an ASM participant during an ASM payment year, CMS, in accordance with paragraph (d) of this section, multiplies the amount otherwise paid under Part B for the covered professional services by the ASM payment multiplier calculated for the ASM participant calculated under paragraph (c) of this section for the corresponding ASM performance year.

(b) *Comparison of ASM participant performance.* For the purpose of determining ASM payment adjustment factors and ASM payment multipliers applicable to adjustments to Part B payments for covered professional services in the corresponding ASM payment year, CMS separately compares final scores of ASM participants in each ASM cohort for the corresponding ASM performance year.

(c) *ASM payment multiplier*. Unless otherwise specified under paragraph (d) of this section, for each ASM participant within an ASM cohort for the applicable ASM payment year, CMS calculates an ASM payment multiplier as 1 plus the ASM payment adjustment factor determined under paragraph (c)(1) of this section.

(1) *ASM payment adjustment factor*. For each ASM participant with a final score greater than zero as described at § 512.745(a)(2)(i) within an ASM cohort for the applicable ASM performance year, CMS calculates an ASM payment adjustment factor using the formula: ASM payment adjustment factor = [(ASM risk level as described in paragraph (c)(1)(i) of this section) × (ASM participant's transformed final score as described in paragraph (c)(1)(ii) of this section) × (scaling factor applicable to the ASM incentive pool as described in paragraph (c)(1)(iv) of this section)] – ASM risk level as described in paragraph (c)(1)(i) of this section. For each ASM participant with a final score equal to zero as described at § 512.745(a)(2)(ii) within an ASM cohort for the applicable ASM payment year, CMS calculates an ASM payment adjustment factor equal to the negative of the applicable ASM level risk level as described in paragraph (c)(1)(i) of this section.

(i) *ASM risk level*. CMS sets an ASM risk level that is the magnitude of the maximum downside and upside risk to which an ASM participant would be subject to during an ASM payment year.

(A) For the 2029 *ASM payment* year, the ASM risk level is 9 percent.

(B) For the 2030 ASM payment year, the ASM risk level is 9 percent.

(C) For the 2031 ASM payment year, the ASM risk level is 10 percent.

(D) For the 2032 ASM payment year, the ASM risk level is 11 percent.

(E) For the 2033 ASM payment year, the ASM risk level is 12 percent.

(ii) *Exchange function and transformed final score.* CMS uses a logistic exchange function with a midpoint set at the median final score of the applicable ASM cohort from the applicable ASM performance year to transform each ASM's participant final score into a numerical value.

(iii) *Incentive pool.* CMS calculates an ASM incentive pool for each ASM cohort for an applicable ASM payment year using the formula: ASM incentive pool = (Sum of Medicare Part B payments for covered professional services paid to ASM participants with final scores in an ASM cohort during the applicable ASM performance year) × (ASM risk level as defined in paragraph (c)(1)(i) of this section) × (ASM redistribution percentage). The ASM redistribution percentage is set at 85 percent.

(iv) *Scaling factor*. CMS calculates a scaling factor for each ASM incentive pool for the applicable ASM payment year that ensures the estimated total payment adjustments would equal the ASM incentive pool. The scaling factor is calculated by dividing the total amount in the ASM incentive pool by the sum of all ASM participant's transformed final scores, multiplied by their respective total Medicare Part B covered professional services payments from the applicable ASM performance year and the applicable ASM risk level as specified under paragraph (c)(1)(i) of this section.

(2) [Reserved]

(d) *No payment adjustments*. CMS assigns an ASM payment adjustment factor of 0 and an ASM payment multiplier of 1 for the applicable ASM payment year that results in no payment adjustment to an ASM participant who does not receive a final score under § 512.745(a)(2)(iii) for the corresponding ASM performance year.

(e) *Notification of ASM payment adjustments to ASM participants.* CMS notifies each ASM participant of their ASM payment adjustment factor and corresponding ASM payment multiplier for the applicable ASM payment year in the ASM performance report under § 512.745(b) provided to each ASM participant for the applicable ASM performance year.

(f) *Change in ASM participant TIN affiliation after ASM performance year and before the end of corresponding ASM payment year.*

(1) CMS adjusts payments to the different TIN using the ASM payment multiplier calculated for the ASM participant based on their performance in the corresponding ASM performance year for an NPI who meets all of the following:

(i) Is an ASM participant with a final score for an ASM performance year.

(ii) Submits Part B covered professional service claims during an ASM payment year using a different TIN than the TIN CMS identified them as an ASM participant for that ASM performance year and to which the ASM participant began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

(2) CMS adjusts claims using the highest ASM payment multiplier from all the TIN and NPI combinations that identified the NPI as an ASM participant for the corresponding ASM performance year for an NPI who meets all of the following:

(i) CMS identifies as an ASM participant under multiple TINs for a given ASM performance year.

(2) Submits Part B covered professional service claims during an ASM payment year under a TIN by which CMS did not identify the ASM participant and to which the ASM participant began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

§ 512.755 Timely error notice process.

(a) *General.* Subject to the limitations on review in § 512.170, an ASM participant may submit a written timely error notice for one or more calculations made and issued by CMS within the ASM performance report if the ASM participant believes an error occurred in calculations due to data quality, misapplication of methodology, or other issues.

(b) *Requirements.* If an ASM participant believes the ASM performance report contains a calculation error as described in paragraph (a) of this section, the ASM participant must submit a written timely error notice, in a form and manner specified by CMS, documenting the calculation error within 30 calendar days of issuance of the ASM performance report, unless specified by CMS.

(1) If the ASM participant does not provide written timely error notice in accordance with paragraph (a) of this section, then the ASM performance report is deemed final 30 calendar days after its issuance.

(2) Only an ASM participant may submit a written timely error notice described in this section.

(3) *Sufficiency of information in written timely error notice.*

(i) CMS determines if the written timely error notice meets the requirements of this section and contains sufficient information to substantiate the request.

(ii) If the request is not compliant with the requirements of this section or requires additional information—

(A) CMS follows up with the ASM participant to request additional information in a form and manner as specified by CMS;

(B) The ASM participant must respond within 10 calendar days of CMS' request for additional information in a form and manner as specified by CMS; and

(C) If an ASM participant does not respond in accordance with paragraph (b)(3)(ii)(B) of this section, then the ASM performance report is deemed final.

(c) *Process.* (1) If CMS receives a written timely error notice within 30 calendar days of the issuance of the ASM performance report that CMS determines meets the requirements of paragraph (b) of this section, CMS issues an initial determination in writing within 30 calendar days of receipt to either confirm that there was an error in the calculation or verify that the calculation is correct.

(2) CMS reserves the right to extend the time for providing its initial final determination upon written notice to the ASM participant.

(d*) Reconsideration request.* An ASM participant who wishes to dispute an initial determination made in accordance with paragraph (c) of the section may invoke the reconsideration review process under § 512.190.

§ 512.760 Data sharing with ASM participants.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), and (e) of this section and certain aggregate data as described in paragraph (d) of this section with ASM participants regarding ASM beneficiaries and performance under the model.

(b) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with ASM participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraph (b)(5) of this section for ASM participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their patients who are ASM beneficiaries.

(2) An ASM participant that wishes to receive beneficiary-identifiable data for its ASM beneficiaries must do all of the following:

(i) Submit a formal request for the data, on at least an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that--

(A) The ASM participant is requesting this beneficiary-identifiable data as part of a covered entity, as defined at 45 CFR 160.103;

(B) The ASM participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the ASM participant to conduct activities described in the first or second paragraph of the definition of health care operations at 45 CFR 164.501; and

(C) The ASM participant's use of beneficiary-identifiable data is limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all ASM beneficiaries under the care of the ASM participant, and that these data are not to be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) To the extent practicable, limit the request to ASM beneficiaries whose claims were used to determine the requesting ASM participant’s eligibility for ASM participation or to whom the requesting ASM participant provided care during an applicable ASM performance year.

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (e)(1) of this section.

(3) CMS shares beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's activities, including but not limited to non-ASM participant parties in collaborative care

arrangements with ASM participants, comply with all appliable laws addressing the appropriate use of data and the confidentiality and privacy of individually identifiable health information and the terms of the data sharing agreement described in paragraph (e)(1) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data includes, when available, the following information:

(i) Unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data used to determine ASM participant eligibility for an applicable ASM performance year; and

(ii) Unrefined (raw) Medicare Parts A, B, and D beneficiary-identifiable claims data for ASM beneficiaries who trigger an applicable EBCM episode with the ASM participant during the applicable ASM performance year.

(c) *Minimum necessary data.* The ASM participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary to accomplish the permitted use of the data. The minimum necessary Medicare Parts A, B, and D data elements may include, but are not limited to the following:

(1) Medicare beneficiary identifier (ID).

(2) Procedure code.

(3) Sex.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) *Aggregated data feedback.* CMS shares aggregated data on one or more select indicators of the ASM participant's performance, de-identified in accordance with 45 CFR 164.514(b), in a form and manner to be specified by CMS, when available, with ASM participants.

(e) *ASM data sharing agreement.*

(1) To retrieve the beneficiary-identifiable data specified in paragraphs (b) and (c) of this section, the ASM participant must complete and submit, on at least an annual basis, a signed ASM data sharing agreement, to be provided in a form and manner and by a date specified by CMS, under which the ASM participant agrees, at a minimum to do all of the following:

(i) Comply with the requirements for use and disclosure of this beneficiary identifiable data that are imposed on covered entities by the HIPAA regulations, including but not limited to 45 CFR part 164, subparts A and E, and the requirements of ASM set forth in this part.

(ii) Comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the ASM data sharing agreement.

(iii) Contractually bind any and all downstream recipients of this beneficiary identifiable data, such as other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including those that meet the definition of a business associate as defined at 45 CFR 160.103 and non-ASM participant parties to collaborative care arrangements described at § 512.771, to the same terms and conditions to which the ASM participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's or non-ASM participant parties' receipt of the beneficiary-identifiable data obtained by the ASM participant.

(iv) That if the ASM participant or any downstream recipient misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may do any or all of the following:

(A) Deem the ASM participant ineligible to obtain the beneficiary-identifiable data under paragraph (b) of this section for any amount of time.

(B) Subject the ASM participant to additional sanctions and penalties available under applicable law.

(v) An ASM participant must comply with all applicable laws and the terms of the data sharing agreement to obtain beneficiary-identifiable data.

(2) CMS shares beneficiary-identifiable data with an ASM participant on the condition that the ASM participant and other individuals or entities performing functions or services related to the ASM participant's data sharing activities, including business associates as defined at 45 CFR 160.103 of the ASM participant and non-ASM participant parties to collaborative care arrangements described at § 512.771, comply with all relevant laws governing the use of data and the privacy and security of individually identifiable health information and the terms of the data sharing agreement described in paragraph (e)(1) of this section.

(f) *Data custodian.* An ASM participant must designate and provide the contact information for, in a form and manner identified by CMS, a data custodian who is responsible for ensuring compliance with privacy and security requirements, including all applicable laws and terms of the ASM data sharing agreement, and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

§ 512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) *Application of the CMS-sponsored model arrangements safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) is available to protect remuneration furnished in accordance with the collaborative care arrangements that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.771.

(b) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect remuneration furnished in ASM in the form of ASM beneficiary engagement incentives that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.770.

§ 512.770 ASM beneficiary incentives.

(a) *ASM beneficiary incentives.* ASM participants may choose to provide in-kind patient engagement incentives, including but not limited to items of technology or services, to ASM beneficiaries, subject to the following conditions:

(1) *Provision of incentive.*

(i) The incentive must be provided directly by the ASM participant or by an agent of the ASM participant under the ASM participant's direction and control to an ASM beneficiary who is an established patient of the ASM participant.

(ii) The ASM participant must be solely responsible for any costs associated with the provision of the incentive, including but not limited to, the retail value of the item or services offered as the ASM beneficiary incentive.

(2) The item or service provided must be reasonably connected to medical care provided by the ASM participant to an ASM beneficiary for an ASM targeted chronic condition.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an ASM beneficiary by engaging the ASM beneficiary in better managing an ASM targeted chronic condition.

(4) The item or service must not be tied to the receipt of items or services outside the services furnished by the ASM participant to the ASM beneficiary.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that an ASM beneficiary may be made aware of the availability of the items or services at the time the ASM beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.

(8) The totality of items or services, including technology as described at paragraph (b) of this section, provided to an ASM beneficiary may not exceed $1,000 in retail value for any one ASM beneficiary.

(b) *Technology provided to an ASM beneficiary.* ASM beneficiary incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to an ASM beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (d) of this section, for an ASM beneficiary.

(2) Items of technology exceeding $75 in retail value must—

(i) Remain the property of the ASM participant; and

(ii) Be retrieved from the ASM beneficiary—

(A) Upon the end of their care relationship with the ASM participant, with documentation of the ultimate date of retrieval. The ASM participant must document all retrieval attempts.

(*1*) In cases when the item of technology is not able to be retrieved, the ASM participant must determine why the item was not retrievable.

(*2*) If it was determined that the item was misappropriated, then the ASM participant must take steps to prevent future beneficiary incentives for that ASM beneficiary.

(*3*) Following this process, documented, diligent, good faith attempts to retrieve items of technology is deemed to meet the retrieval requirement; or

(B) If the provided technology breaks or is otherwise rendered unusable for its intended purposes, with documentation of the ultimate date of retrieval. The ASM participant may replace the unusable unit with the same or similar technology, to the extent practicable, that meets the requirements of paragraphs (a) and (b) of this section.

(c) *Documentation of ASM beneficiary incentives*. In addition to requirements at § 512.135 of this part ASM participants must do all of the following:

(1) Maintain documentation of items and services furnished as beneficiary incentives that exceed $75 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the ASM beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(2)(ii) of this section.

(4) The ASM participant must retain and provide access to the required documentation.

(d) Clinical goals of *ASM*. The following are the clinical goals of ASM, which may be advanced

through ASM beneficiary incentives:

(1) Promoting preventive care through improved management of ASM targeted chronic conditions.

(2) Empowering patients to actively participate and be accountable for quality and whole health outcomes.

(3) Facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

§ 512.771 Collaborative care arrangements.

(a) *General*. Collaborative care arrangements must meet all of the following:

(1) Be in writing, signed by both parties, and contain the effective date of the arrangement.

(2) Be exclusively between the ASM participant and the primary care practice with whom the ASM participant shares at least one established patient who is an ASM beneficiary.

(3) The collaborative care arrangement must be entered into for the purpose of either of the following:

(i) Furthering the ASM participant's performance in the improvement activities ASM performance category at § 512.735.

(ii) Advancing the clinical goals of ASM as described in paragraph (b) of this section.

(4) Participation in a collaborative care arrangement must be voluntary and without penalty for nonparticipation.

(5) Both parties to the collaborative care arrangement must comply with all applicable statutes, regulations, and guidance, including without limitation the following:

(i) Federal criminal laws.

(ii) The False Claims Act (31 U.S.C. 3729 et seq.).

(iii) The anti-kickback statute (42 U.S.C. 1320a-7b(b)).

(iv) The civil monetary penalties law (42 U.S.C. 1320a-7a).

(v) The physician self-referral law (42 U.S.C. 1395nn).

(6) The opportunity to enter into a collaborative care arrangement, and the amount of any payment under a collaborative care arrangement, must not be conditioned directly or indirectly on the

volume or value of past or anticipated referrals or business generated by, between, or among the parties to the collaborative care arrangement or any other person.

(7) Any payment between the parties set forth in a collaborative care arrangement must not exceed the sum total of the payment adjustments made to an ASM participant's claims for a given ASM performance year as a result of the application of the ASM payment adjustment factor to the ASM participant's Medicare Part B payments for covered professional services during an ASM payment year.

(8) Any payment or other remuneration set forth in the collaborative care arrangement must be solely between the parties to the arrangements. Any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.

(9) Both parties to the collaborative care arrangement must retain the ability to make decisions in the best interests of ASM beneficiaries, including the selection of clinicians, devices, supplies, and treatments.

(10) The collaborative care arrangement must not do either of the following:

(i) Induce any party to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(11) ASM participants must maintain contemporaneous documentation, in accordance with § 512.135, regarding all collaborative care arrangements entered into, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any payments between the parties.

(iii) A description of the methodology and accounting formula for determining the amount of any payments between the parties.

(12) The collaborative care arrangement must stipulate that any non-ASM participant party is considered a downstream recipient for CMS data sharing purposes, and must require the non-ASM participant party to comply with applicable data sharing requirements at § 512.760.

(13) Any non-ASM participant party to a collaborative care arrangement must be a downstream participant subject to the standard provisions for Innovation Center models specified in subpart A of this part 512.

(b) *Clinical goals of ASM*. The following are the clinical goals of ASM, which may be advanced

through collaborative care arrangements:

(1) Promoting preventive care through improved management of ASM targeted chronic conditions.

(2) Empowering patients to actively participate and be accountable for quality and whole health outcomes.

(3) Facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

(c) C*ollaborative care arrangement exclusions*. An ASM participant may not enter into a collaborative care arrangement with a party that is excluded from participation in any Federal health care programs by the Inspector General.

§ 512.775 Medicare program waivers.

(a) *Medicare payment waivers*. Unless otherwise specified in § 512.710(a)(2), CMS waives the requirements of section 1848(q) of the Act, and its implementing regulations, for an ASM participant for each ASM performance year that the ASM participant meets the ASM eligibility criteria set forth in § 512.710(b)(1).

(b) *Waiver of certain telehealth requirements.*

(1) *Waiver of the geographic site requirements*. Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for ASM participants and ASM beneficiaries solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are medically appropriate for treatment of an ASM targeted chronic condition.

(2) *Waiver of the originating site requirements*. Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)I(ii)(I) through (VIII) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are medically appropriate for treatment of an ASM targeted chronic condition.

(3) *Waiver of selected payment provisions*. CMS waives payment requirements as follows:

(i) Under section 1834(m)(2)(A) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(ii) Under section 1834(m)(2)(B) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to ASM.

(4) *Other requirements*. All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

§ 512.780 Extreme and uncontrollable circumstances.

(a) *General rule*. Except as specified in paragraph (b) of this section, CMS—

(1) Applies determinations made under the Quality Payment Program for whether an extreme and uncontrollable circumstance has occurred and the affected area during the ASM performance year; and

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred.

(b) *Additional criteria.*

(1) CMS has sole discretion to determine, based on information known to the agency prior to the beginning of the relevant ASM payment year, that data for an ASM participant are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents, including third-party intermediaries.

(2) CMS notifies ASM participants of the following:

(i) Its determination that the circumstances described at paragraph (b)(1) of this section exist; and

(ii) The impact of the circumstances described in paragraph (b)(1) of this section upon scoring methodology for affected ASM participants in a form and manner determined by CMS.

(c) *Impact on final scores.*

(1) Except as described in paragraph (c)(2) of this section, an ASM participant who CMS identified as having been affected by a circumstance described in paragraphs (a) or (b) of this section is exempt from meeting data submission requirements identified at § 512.720 and does not receive a final score, resulting in a neutral payment adjustment for the corresponding ASM payment year.

(2) In the event that an ASM participant who CMS identified as having been affected by a circumstance described in paragraph (a) or (b) of this section submits data in accordance with the data submission requirements at § 512.720, CMS assigns the ASM participant a final score using the methodology described at § 512.745 for the applicable ASM performance year.

Robert F. Kennedy, Jr.

Secretary,

Department of Health and Human Services.

Note: The following Appendices will not appear in the **Code of Federal Regulations**.

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures and specialty measure sets will continue to apply for the CY 2026 performance period/2028 MIPS payment year and future years. Previously finalized measures and specialty sets are in the CY 2017 through CY 2025 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, and 89 FR 98599 through 98957. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a Consensus-Based Entity (CBE) are shown in Table A of this Appendix as follows: CBE # /CBE / eCQM CBE #.

Table Group A: New MIPS Quality Measures Finalized for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

A.1. Patient Reported Falls and Plan of Care

Category	**Description**
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	513
Description:	Percentage of patients (or caregivers as appropriate) with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who reported a fall occurred and those that fell had a plan of care for falls documented at every visit.
Measure Steward:	American Academy of Neurology
Numerator:	1. Patients (or caregivers as appropriate) that reported a fall occurred since the last visit and 2. Patients who had a falls plan of care documented at every visit.
Denominator:	1. Patients with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke. 2. Patients with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who report (or caregiver as appropriate) a fall occurred since last visit.
Exclusions:	None
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this process measure because it addresses patient safety in an at-risk population by ensuring patients with an active diagnosis of a neurological disorder are screened for falls and have a falls plan of care established. Studies that focus on the rate of falls for common neurological conditions indicate falls are an issue for neurology patients with symptomology that affects movement and balance, necessitating the need to ensure these patients are screened for falls and an appropriate plan of care is established. According to the World Health Organization (WHO), falls are the second leading cause of mortality worldwide.[489] [490] Studies have revealed that patients with neurodegenerative conditions like dementia or cognitive impairment have a 2–8-fold higher chance of falls when compared to those with normal cognition.[491] [492] [493] Additionally, patients with Parkinson's disease (PD) have a five times higher risk of fall-related injuries.[494] [495] Fall incidence is reported 2–4 times higher in patients with neurological disorders than in healthy subjects of similar age, and 46 percent of neurological patients reveal having had one or more falls per year.[496] [497] [498] [499] This measure is predicated on evidence-based clinical guidelines that recommend exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at an increased risk for falls.[500] The measure will enhance compliance with the clinical guidelines by incentivizing clinicians to assess falls and develop an appropriate care plan to help reduce fall incidence, thereby improving patient safety and outcomes. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee recommended this measure, which has been fully developed and tested at the clinician level with high reliability based upon signal-to-noise scores and adequate face validity. Testing of measure performance indicated a gap in care, with a median performance rate of 89 percent, which allows room for improvement among clinicians treating this patient population. This measure was previously available in MIPS as a QCDR measure (AAN34), which was in the previously finalized Neurodegenerative Conditions MVP, and substantiates the feasibility for implementation in MIPS. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. This measure could be added to the Quality Care for Patients with Neurologic Conditions MVP in the future and will fill a current quality measure inventory gap within the neurological clinical topic area. Additionally, it will provide a specialty specific measure for the MIPS Neurology specialty set under Table B.23 of this Appendix. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Patient Reported Falls and Plan of Care measure. A commenter noted it aligns with the occupational therapy scope of practice, including risk evaluation and individualized care planning. Another commenter supported the measure because it targets a narrower patient population with neurological conditions than measure Q155: Falls: Plan of Care. Commenters emphasized falls are common in this population and often cause

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[489] Manorenj, Sandhya & Shaik, Reshma. (2024). A Neurologist's Perspective of Approach to Falls in the Elderly. *Annals of Movement Disorders, 7*, 3-12. https://doi.org/10.4103/aomd.aomd_56_22.
[490] Masud, T., & Morris, R. O. (2001). Epidemiology of Falls. *Age and Ageing, 30 Suppl 4*, 3–7. https://doi.org/10.1093/ageing/30.suppl_4.3.
[491] See footnote Manorenj et al., 2024.
[492] Delbaere, K., Kochan, N. A. , Close, J. C., Menant, J. C. , Sturnieks, D. L. , Brodaty, H. , Sachdev, P. S. & Lord, S. R. (2012). Mild Cognitive Impairment as a Predictor of Falls in Community-Dwelling Older People. *American Journal of Geriatric Psychiatry, 20*(10), 845-853. https://doi.org/10.1097/JGP.0b013e31824afbc4.
[493] Allan, L. M., Ballard, C. G., Rowan, E. N., & Kenny, R. A. (2009). Incidence and Prediction of Falls in Dementia: A Prospective Study in Older People. *PloS One*, *4*(5), e5521. https://doi.org/10.1371/journal.pone.0005521.
[494] See footnote Manorenj et al., 2024.
[495] Pelicioni, P. H. S., Menant, J. C., Latt, M. D., & Lord, S. R. (2019). Falls in Parkinson's Disease Subtypes: Risk Factors, Locations and Circumstances. *International Journal of Environmental Research and Public Health*, *16*(12), 2216. https://doi.org/10.3390/ijerph16122216.
[496] Ehrhardt, A., Hostettler, P., Widmer, L., Reuter, K., Petersen, J. A., Straumann, D., & Filli, L. (2020). Fall-Related Functional Impairments in Patients with Neurological Gait Disorder. *Scientific Reports*, *10*(1), 21120. https://doi.org/10.1038/s41598-020-77973-4.
[497] Stolze, H., Klebe, S., Zechlin, C., Baecker, C., Friege, L., & Deuschl, G. (2004). Falls in Frequent Neurological Diseases--Prevalence, Risk Factors and Aetiology. *Journal of Neurology*, *251*(1), 79–84. https://doi.org/10.1007/s00415-004-0276-8.
[498] Xu, T., Clemson, L., O'Loughlin, K., Lannin, N. A., Dean, C., & Koh, G. (2018). Risk Factors for Falls in Community Stroke Survivors: A Systematic Review and Meta-Analysis. *Archives of Physical Medicine and Rehabilitation*, *99*(3), 563–573.e5. https://doi.org/10.1016/j.apmr.2017.06.032.
[499] Homann, B., Plaschg, A., Grundner, M., Haubenhofer, A., Griedl, T., Ivanic, G., Hofer, E., Fazekas, F., & Homann, C. N. (2013). The Impact of Neurological Disorders on the Risk for Falls in the Community Dwelling Elderly: A Case-Controlled Study. *BMJ Open*, *3*(11), e003367. https://doi.org/10.1136/bmjopen-2013-003367.
[500] US Preventive Services Task Force, Grossman, D. C., Curry, S. J., Owens, D. K., Barry, M. J., Caughey, A. B., Davidson, K. W., Doubeni, C. A., Epling, J. W., Jr, Kemper, A. R., Krist, A. H., Kubik, M., Landefeld, S., Mangione, C. M., Pignone, M., Silverstein, M., Simon, M. A., & Tseng, C. W. (2018). Interventions to Prevent Falls in Community-Dwelling Older Adults: US Preventive Services Task Force Recommendation Statement. *JAMA*, *319*(16), 1696–1704. https://doi.org/10.1001/jama.2018.3097.

preventable hospitalizations, loss of independence, and higher mortality. Clinicians play an essential role in developing care plans and connecting patients with appropriate services to prevent falls. A commenter encouraged broader adoption across specialties.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: A commenter supported this new measure as an optional measure in MIPS and agreed it is appropriate for attribution to neurologists. The commenter recommended that CMS and the measure steward ensure the definition of "plan of care" remains flexible and clinically appropriate, allowing physicians to tailor interventions based on individual patient needs, preferences, and risk factors. The commenter urged CMS to consider the following issues: administrative burden; clear attribution to neurologists; visit frequency; and caregiver involvement. The commenter encouraged CMS to refine the new measure to ensure it is practical, equitable, and aligned with clinical practice.

Response: We thank the commenter for supporting this new measure. The current measure specification provides a definition of what a plan of care for falls must include. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. The measure will contain coding specific to the diagnoses included in the denominator consistent with patients cared for by neurologists and is determined to be low burden to report. The measure is to be reported at each visit as falls within this patient population are common, and the intent is for ongoing assessment by clinicians as well as collaboration with other clinicians and professionals who participate in implementation of the plan of care.

Comment: A commenter emphasized the need to account for varying patient populations and care contexts and recommended that CMS continue to assess measure specifications and risk-adjustment methodologies to ensure that this new measure, in addition to other outcome-based measures, reflects differences in patient acuity and resource needs.

Response: We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. In addition, CMS completes measure analysis annually to determine potential measure updates for future performance periods. This measure was not tested with any risk adjustment variables, and the measure developer did not recommend stratification at this time. We also note that process measures are not typically risk adjusted.[501]

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32874 through 32875), we are finalizing the *Patient Reported Falls and Plan of Care* measure as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[501] Centers for Medicare & Medicaid Services. Risk Adjustment & Stratification. https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/risk.

A.2. Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)[502]

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	512
Description:	The number of prevalent dialysis patients in a practitioner group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1 - "Patients who were on dialysis and had documentation of status at the end of the year." Numerator 2 - "The ratio of the observed number of waitlist events in a practitioner group to the model-based expected number of waitlist events."
Denominator:	Denominator 1 - "Patients age less than 75 years who are on dialysis during the performance period prior." Denominator 2 - "The denominator for the Prevalent Standardized Waitlist Ratio (PSWR) is the total number of patients on dialysis under the age of 75 in the practitioner group according to each patient's treatment history each year."
Exclusions:	Patients admitted to a skilled nursing facility (SNF) during the period of evaluation. Patients in hospice in the year before or during the period of evaluation. Patients with a diagnosis for dementia in the year before or during the period of evaluation. The noted exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data. Patients who were attributed to dialysis practitioner groups with fewer than 11 patients or 2 expected events are not excluded from the measure. If a provider cannot be matched to a TIN, patients will be grouped into a separate 'null' TIN and still included in the models but are not summarized to any valid individual TINs. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[502] The measure title was revised from the MERIT submission to include 'kidney transplant' for clarity.

Category	Description
Rationale:	Starting with the CY 2025 performance period/2027 MIPS payment year, we finalized measure Q510: First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR) and measure Q511: Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW) (89 FR 98616 through 98623). Both measures track dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Measure Q510 tracks the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant for patients within the first year after dialysis initiation, with the objective of providing access to kidney transplant in a timely manner within that first year after starting dialysis, which is associated with improved outcomes. Measure Q511 tracks the number of patients on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant for all dialysis patients in a dialysis practitioner or group practice to encourage ongoing attention to transplantation as a treatment option. Measure Q511 also assesses the waitlist each month for active status of patients on the kidney transplant waitlist, which encourages ongoing optimization of health to maintain active status and ensure patients are ready to accept a kidney when a match becomes available. Measure Q511 works in tandem with measure Q510 to assess both initial and on-going care. We proposed the PSWR process measure for the CY 2026 performance period/2028 MIPS payment year because it builds on the previous measures (Q510 and Q511) by assessing new placement on the kidney or kidney-pancreas transplant waitlist or receipt of a living donor transplant for all dialysis patients. End-stage renal disease (ESRD) affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures.[503] While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant.[504] This measure assesses whether patients who are on dialysis and found to be an expected waitlist event based upon the Cox model, were placed on either the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicates a performance gap for a process that can be directly linked to improved patient outcomes. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners followed by subsequent patient transplant wait listing. For example, clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the State of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[505] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[506] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation based on reporting on the Medical Evidence Form 2728 (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf) and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[507] Approximately 30 percent of patients were uninformed about kidney transplantation, which was associated with half the rate of access to transplantation compared to patients who were informed.[508] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients. The provision of such information was associated with a nearly threefold increase in the likelihood of waitlisting.[509] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist, or receipt of a living donor transplant for patients on dialysis, with the objective of improving their overall health. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Waitlisting is a direct step in the process of transplantation which drives quality by progressing patients towards the goal of transplantation and better health outcomes.

[503] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). (2023). Kidney Disease Statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.
[504] Wouk N. (2021). End-Stage Renal Disease: Medical Management. *American Family Physician*, *104*(5), 493–499. https://www.aafp.org/pubs/afp/issues/2021/1100/p493.pdf.
[505] Paul, S., Plantinga, L. C., Pastan, S. O., Gander, J. C., Mohan, S., & Patzer, R. E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. *Clinical Journal of the American Society of Nephrology: CJASN*, *13*(2), 282–289. https://doi.org/10.2215/CJN.04690417.
[506] See footnote Paul et al., 2018.
[507] Kucirka, L. M., Grams, M. E., Balhara, K. S., Jaar, B. G., & Segev, D. L. (2012). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *12*(2), 351–357. https://doi.org/10.1111/j.1600-6143.2011.03865.x.
[508] See footnote Kucirka et al., 2012.
[509] Salter, M. L., Orandi, B., McAdams-DeMarco, M. A., Law, A., Meoni, L. A., Jaar, B. G., ... & Segev, D. L. (2014). Patient-and Provider-Reported Information about Transplantation and Subsequent Waitlisting. *Journal of the American Society of Nephrology, 25*(12), 2871-2877. https://doi.org/10.1681/ASN.2013121298.

Category	Description
	A measure focusing on the outcome of waitlisting is appropriate for several reasons. First, in preparing patients for suitability for waitlisting, dialysis practitioners optimize their health and functional status, improving their overall health state. Second, waitlisting is a necessary step prior to potential receipt of a deceased donor kidney transplant (receipt of a living donor kidney is also accounted for in the measure), which is known to be beneficial for survival and quality of life.[510] Third, dialysis practitioners exert substantial control over the processes that result in waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation and assisting patients with completion of the transplant evaluation process, in order to increase their candidacy for transplant waitlisting. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. Finally, wide regional and facility variations in waitlisting rates highlight substantial room for improvement for this measure.[511] [512] [513] [514] Additionally, this measure focuses specifically on the population of prevalent patients on dialysis, examining for the occurrence of new waitlisting or living donor transplant events. This will evaluate and encourage rapid attention from dialysis practitioner groups to the optimization of health of patients to ensure early access to the waitlist, which has been demonstrated to be particularly beneficial.[515] [516] [517] [518] Given that many patients may not be ready for transplant candidacy immediately following initiation of dialysis, this measure encourages ongoing attention to transplant candidacy throughout a patient's time on dialysis. The PRMR did not reach consensus for this measure with concerns regarding exclusions for patients opting out of waitlisting and attribution. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. As discussed above, studies suggest a significant positive correlation between the clinician activities and the addition of patients to a transplant waitlist, which are necessary for patients to receive the improved outcomes associated with kidney transplants. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed addition of the Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR) measure to MIPS. The commenter noted this measure will build on the previous transplant measures to assess successful placement on the kidney or kidney-pancreas transplant waitlist or receipt of a living donor transplant. This will help payers understand if clinicians are connecting patients who have ESRD with the additional care and support they need to prepare for organ transplant. These measures could help ensure clinicians are working with patients to help them access transplant waitlists and if facilities are proactively reaching out to patients on the waitlist and helping them achieve transplantation.

Response: We thank the commenter for supporting this new measure in MIPS.

Comment: A few commenters opposed the addition of the PSWR measure, explaining that waitlisting decisions are made primarily by transplant centers and patients rather than nephrologists, making the measure inappropriate at the clinician/group

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[510] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *11*(10), 2093–2109. https://doi.org/10.1111/j.1600-6143.2011.03686.x.

[511] Ashby, V. B., Kalbfleisch, J. D., Wolfe, R. A., Lin, M. J., Port, F. K., & Leichtman, A. B. (2007). Geographic Variability in Access to Primary Kidney Transplantation in the United States, 1996-2005. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *7*(5 Pt 2), 1412–1423. https://doi.org/10.1111/j.1600-6143.2007.01785.x.

[512] Satayathum, S., Pisoni, R. L., McCullough, K. P., Merion, R. M., Wikström, B., Levin, N., Chen, K., Wolfe, R. A., Goodkin, D. A., Piera, L., Asano, Y., Kurokawa, K., Fukuhara, S., Held, P. J., & Port, F. K. (2005). Kidney Transplantation and Wait-listing Rates from the International Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney International*, *68*(1), 330–337. https://doi.org/10.1111/j.1523-1755.2005.00412.x.

[513] Patzer, R. E., Plantinga, L., Krisher, J., & Pastan, S. O. (2014). Dialysis Facility and Network Factors Associated with Low Kidney Transplantation Rates among United States Dialysis Facilities. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *14*(7), 1562–1572. https://doi.org/10.1111/ajt.12749.

[514] Melanson, T. A., Gander, J. C., Rossi, A., Adler, J. T., & Patzer, R. E. (2021). Variation in Waitlisting Rates at the Dialysis Facility Level in the Context of Goals for Improving Kidney Health in the United States. *Kidney International Reports*, *6*(7), 1965–1968. https://doi.org/10.1016/j.ekir.2021.04.031.

[515] Meier-Kriesche, H. U., & Kaplan, B. (2002). Waiting Time on Dialysis as the Strongest Modifiable Risk Factor for Renal Transplant Outcomes: A Paired Donor Kidney Analysis. *Transplantation*, *74*(10), 1377–1381. https://doi.org/10.1097/00007890-200211270-00005.

[516] Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., Leichtman, A. B., & Kaplan, B. (2000). Effect of Waiting Time on Renal Transplant Outcome. *Kidney International*, *58*(3), 1311–1317. https://doi.org/10.1046/j.1523-1755.2000.00287.x.

[517] Schold, J. D., Huml, A. M., Poggio, E. D., Sedor, J. R., Husain, S. A., King, K. L., & Mohan, S. (2021). Patients with High Priority for Kidney Transplant Who Are Not Given Expedited Placement on the Transplant Waiting List Represent Lost Opportunities. *Journal of the American Society of Nephrology: JASN*, *32*(7), 1733–1746. https://doi.org/10.1681/ASN.2020081146.

[518] Schold, J. D., & Meier-Kriesche, H. U. (2006). Which Renal Transplant Candidates Should Accept Marginal Kidneys in Exchange for a Shorter Waiting Time on Dialysis? *Clinical Journal of the American Society of Nephrology: CJASN*, *1*(3), 532–538. https://doi.org/10.2215/CJN.01130905.

level. Commenters noted that the measure has not received CBE endorsement and was not recommended in the 2024–2025 PRMR due to concerns with validity, insufficient exclusions, and risk of incorrect attribution. The commenters warned that linking the measure to accountability programs could pressure patients into enrolling and create disparities given variable transplant center criteria. One of the commenters added that because MIPS benchmarking assumes 100 percent performance, a measure designed to identify outliers, or a measure not expected to achieve full performance, should not be included in MIPS. Another commenter suggested that CMS instead adopt measures that better reflect nephrologists' roles, such as referral or initiation of the evaluation process.

Response: We thank the commenters for their feedback. While we acknowledge there are aspects of this measure that are not directly in the clinician/group's control, the outcome can be influenced through coordination of care, strong communication with transplant centers and advocacy for patients, and optimization of a patient's overall health and comorbid conditions.[519] While determining transplantation candidacy is complex and multidisciplinary, the referring nephrologist remains cardinal to this process, as the most significant barrier to pre-emptive kidney transplantation is timely referral to the transplantation program.[520] [521] It is incumbent on all caregivers involved in the care of a patient to work towards the goals of transplant referral if decided by the patient, successful completion of the transplant evaluation resulting in waitlisting, and maintenance on the waitlist to remain eligible to receive a kidney. In regard to an exclusion for patients who chose not to consider transplantation, we recognize the decision to pursue kidney transplant as a kidney replacement modality is a multifaceted, individual decision. However, it is difficult to account for patient choice in the measure given the measure's construction and risk adjustment methodology. Based on the literature, we expect this to be a small number of patients who may be found across dialysis centers, thus affecting each at a similar rate and being an area of great interest for future work.[522] [523]

While we agree CBE endorsement is preferred, this measure should nonetheless be added to MIPS as it meets the statutory standard for inclusion as a non-endorsed measure Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. Being added to and maintained on the waitlist for kidney transplantation is the culmination of a variety of preceding preparatory activities and the continuation of patient advocacy and health optimization, which may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the overall health of the patient while on dialysis. There is a significant association between the clinician activities described in this measure and the addition and maintenance of patients to a transplant waitlist, which is necessary for patients to receive the improved health outcomes associated with kidney transplant.[524] Inclusion of this measure in MIPS also aligns with the ESRD Quality Incentive Program as indicated in a prior response. The benchmark for this measure will be based on the ratio of the observed number of waitlist events in a practitioner group to the model-based expected number of waitlist events. All data reported will be used to create the benchmark for scoring purposes, and clinicians will be assessed based upon this benchmark.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32876 through 32879), we are finalizing the *Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)* measure as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[519] Moe, S. M., Brennan, D. C., Doshi, M. D., Gaston, R. S., Gurley, S. B., Mujtaba, M. A., Schmidt, R. J., Segal, M. S., Tucker, J. K., Wiseman, A. C., & Josephson, M. A. (2022). The Importance of Transplant Nephrology to a Successful Kidney Transplant Program. *Clinical Journal of the American Society of Nephrology : CJASN*, *17*(9), 1403–1406. https://doi.org/10.2215/CJN.02000222.

[520] Virmani, S., & Asch, W. S. (2020). The Role of the General Nephrologist in Evaluating Patients for Kidney Transplantation: Core Curriculum 2020. *American Journal of Kidney Diseases: The Official Journal of the National Kidney Foundation*, *76*(4), 567–579. https://doi.org/10.1053/j.ajkd.2020.01.001.

[521] See footnote Salter et al., 2014.

[522] Lentine, K. L., Smith, J. M., Miller, J. M., Bradbrook, K., Larkin, L., Weiss, S., Handarova, D. K., Temple, K., Israni, A. K., & Snyder, J. J. (2023). OPTN/SRTR 2021 Annual Data Report: Kidney. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *23*(2 Suppl 1), S21–S120. https://doi.org/10.1016/j.ajt.2023.02.004.

[523] See footnote Salter et al., 2014.

[524] See footnote Salter et al., 2014.

A.3. Diagnostic Delay of Venous Thromboembolism in Primary Care

Category	Description
CBE # / eCQM CBE #:	N/A / 3749e
Quality #:	514
Description:	Percentage of episodes for patients 18 years of age and older with documented Venous Thromboembolism (VTE) symptoms in the primary care setting and who had a diagnosis of VTE that occurs >24 hours and within 30 days following the index primary care visit where symptoms for the VTE were first present.
Measure Steward:	Brigham and Women's Hospital
Numerator:	All qualified VTE encounters in which the VTE diagnosis occurs greater than 24 hours and within 30 days following the index PCP visit.
Denominator:	All Qualified VTE Encounters in which the patient was aged 18 or older at the start of the Qualified VTE Encounter.
Exclusions:	Exclude qualified VTE encounter with a hospice care service documented within previous 90 Days Exclude qualified VTE encounter with a palliative care service documented within previous 90 Days Exclude qualified VTE encounter with another qualified VTE encounter documented within previous 6 months
Measure Type:	Intermediate Outcome
High Priority Measure:	Yes
Collection Type:	eCQM
Measure-Specific Case Minimum/Performance Period:	This eCQM is intended to be reported by integrated health systems with access to both ambulatory and inpatient documentation.

Category	Description
Rationale:	We proposed this intermediate outcome measure because measuring and reporting delayed VTE diagnosis rates will inform health care providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by patients. This measure has the potential to lower health care costs associated with VTE by providing ongoing patient outcome data that can be used to improve VTE diagnostic performance and to reduce complications associated with delayed diagnosis and treatment. This eCQM is intended to be reported by integrated health systems with access to both ambulatory and inpatient documentation. VTE is a serious, preventable public health problem affecting approximately 300,000–600,000 individuals in the U.S. each year.[525] Without timely and adequate treatment, the likelihood of significant complications increases.[526] VTE (pulmonary embolism and deep vein thrombosis) has a 30-day mortality rate as high as 23 percent[527] [528] and because signs and symptoms of VTE can be non-specific, timely diagnosis of VTE is difficult, leading to missed VTE diagnosis. Two studies of autopsies in large hospitals found that 9-12 percent had VTE, and 84-91 percent were undiagnosed at the time of death.[529] [530] In addition to concerns over patient safety, VTE events are costly to healthcare systems. One study estimated that costs associated with VTE complications ranged from $426-$41,133 across literature, imposing a financial burden on healthcare systems.[531] Timely diagnosis of VTE events may prevent resulting adverse events from occurring, with the potential to save healthcare costs and reduce the mortality rate. Empirical evidence supports a marked difference in mortality between patients who receive immediate diagnosis and treatment of VTE and those who are left undiagnosed.[532] VTEs are associated with a high 30-day mortality rate[533] and delays in VTE diagnosis are associated with higher rates of complications and an increased risk of mortality.[534] Earlier diagnosis of VTE may reduce the morbidity and mortality associated with the dangerous condition[535] [536] and could promote positive patient outcomes. This evidence supports this measure by highlighting the increased morbidity and mortality associated with the delayed diagnosis of VTE, which affirms the potential value of this measure to reduce any delay in VTE diagnosis. This measure could be added to the Value in Primary Care MVP in the future and could be a potential addition to the MIPS Family Medicine, Geriatrics, and Internal Medicine specialty sets under Tables B.13, B.16, and B.19 of this Appendix. The PRMR Clinician Recommendation Committee recommended this measure with the condition that implementation burdens are addressed for facilities with less sophisticated EHRs. This measure was endorsed by the CBE as CBE 3749e. While concerns were discussed regarding EHR implementation, we have determined the measure is feasible for implementation in MIPS as an eCQM by integrated health systems, and this measure is an important clinical topic for primary care clinicians to facilitate timely diagnosis of VTE. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed addition of the Diagnostic Delay of Venous Thromboembolism in Primary Care measure in MIPS to promote prompt diagnosis and referral to a venous thromboembolism (VTE) specialist for appropriate

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[525] Beckman, M. G., Hooper, W. C., Critchley, S. E., & Ortel, T. L. (2010). Venous Thromboembolism: A Public Health Concern. *American Journal of Preventive Medicine*, *38*(4 Suppl), S495–S501. https://doi.org/10.1016/j.amepre.2009.12.017.
[526] See footnote Beckman et al., 2010.
[527] Tagalakis, V., Patenaude, V., Kahn, S. R., & Suissa, S. (2013). Incidence of and Mortality from Venous Thromboembolism in a Real-World Population: The Q-VTE Study Cohort. *The American Journal of Medicine*, *126*(9), 832.e13–832.e8.32E21. https://doi.org/10.1016/j.amjmed.2013.02.024.
[528] Nijkeuter, M., Söhne, M., Tick, L. W., Kamphuisen, P. W., Kramer, M. H., Laterveer, L., van Houten, A. A., Kruip, M. J., Leebeek, F. W., Büller, H. R., Huisman, M. V., & Christopher Study Investigators (2007). The Natural Course of Hemodynamically Stable Pulmonary Embolism: Clinical Outcome and Risk Factors in a Large Prospective Cohort Study. *Chest*, *131*(2), 517–523. https://doi.org/10.1378/chest.05-2799.
[529] Karwinski, B., & Svendsen, E. (1989). Comparison of Clinical and Postmortem Diagnosis of Pulmonary Embolism. *Journal of Clinical Pathology*, *42*(2), 135–139. https://doi.org/10.1136/jcp.42.2.135.
[530] Carvalho Bricola, S. A., Paiva, E. F., Lichtenstein, A., Gianini, R. J., Duarte, J. G., Shinjo, S. K., Eluf-Neto, J., & Arruda Martins, M. (2013). Fatal Pulmonary Embolism in Hospitalized Patients: A Large Autopsy-based Matched Case-control Study. *Clinics (Sao Paulo, Brazil)*, *68*(5), 679–685. https://doi.org/10.6061/clinics/2013(05)16.
[531] Ruppert, A., Steinle, T., & Lees, M. (2011). Economic Burden of Venous Thromboembolism: A Systematic Review. *Journal of Medical Economics*, *14*(1), 65–74. https://doi.org/10.3111/13696998.2010.546465.
[532] Liederman, Z., Chan, N., & Bhagirath, V. (2020). Current Challenges in Diagnosis of Venous Thromboembolism. *Journal of Clinical Medicine*, *9*(11), 3509. https://doi.org/10.3390/jcm9113509.
[533] See footnote Tagalakis et al., 2013.
[534] Klok, F. A., Barco, S., Konstantinides, S. V., Dartevelle, P., Fadel, E., Jenkins, D., Kim, N. H., Madani, M., Matsubara, H., Mayer, E., Pepke-Zaba, J., Delcroix, M., & Lang, I. M. (2018). Determinants of Diagnostic Delay in Chronic Thromboembolic Pulmonary Hypertension: Results from the European CTEPH Registry. *The European Respiratory Journal*, *52*(6), 1801687. https://doi.org/10.1183/13993003.01687-2018.
[535] Dalen J. E. (2002). Pulmonary Embolism: What Have We Learned Since Virchow? Natural History, Pathophysiology, and Diagnosis. *Chest*, *122*(4), 1440–1456. https://doi.org/10.1378/chest.122.4.1440.
[536] Ozsu, S., Oztuna, F., Bulbul, Y., Topbas, M., Ozlu, T., Kosucu, P., & Ozsu, A. (2011). The Role of Risk Factors in Delayed Diagnosis of Pulmonary Embolism. *The American Journal of Emergency Medicine, 29*(1), 26–32. https://doi.org/10.1016/j.ajem.2009.07.005.

treatment. The commenter suggested CMS further underscore the dire consequences of VTE in the rationale section by adding the following language: VTE is the third leading cause of cardiovascular death, after heart attack and stroke.[537] Another commenter supported this new measure, stating that it reflects ongoing movement toward interoperability and more timely performance data.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: Several commenters opposed this new measure citing the following reasons:

- Applicability and Scope: The commenters stated that the measure should extend beyond primary care settings, such as urgent care, given workforce shortages and the wide range of patient entry points. They added that the measure would be better suited for internal quality improvement initiatives or integrated delivery networks rather than being applied within MIPS or other value-based programs.
- Clinical Feasibility and Fairness: The commenters expressed concern that the measure could unfairly penalize clinicians who do not have access to rapid (within 24 hours) ultrasound services, noting that this time interval is impractical in many settings. They added that the measure may also penalize clinicians for diagnostic delays that are clinically reasonable.
- Risk of Overuse/Defensive Medicine: A commenter cautioned that the measure could incentivize overuse of VTE diagnostics, lead to unnecessary emergency department visits, and encourage defensive medicine, ultimately increasing healthcare costs.
- Measure Design Concerns: The commenters stated that the measure lacks risk stratification and includes an overly broad symptom list (for example, cough) that overlaps with many conditions, making timely and accurate diagnosis challenging. They also noted that the denominator requires several symptoms or codes in the same encounter, which may exclude legitimate cases, such as when a primary care clinician makes the diagnosis, but imaging is performed elsewhere. In addition, commenters indicated that the definitions of "qualified VTE encounters" and "index primary care visit" are unclear, and the measure lacks sufficient evidence to attribute delays to clinicians based on a single symptom.
- Measure Specifications: The commenters noted that ICD, CPT, and RxNorm codes must all appear within the same encounter. The measure appears to restrict the denominator to emergency department–diagnosed cases while excluding situations where a primary care clinician initiates the diagnosis and subsequent imaging or anticoagulation occurs later. They also raised questions about the consequences for reporting if a diagnosis is initially missed.
- Testing and Reliability Issues: The commenters noted that reliability fell below the threshold (~60 percent of entities). Signal-to-noise ratio at the group level was 0.37512 (minimum) and 0.5393 (median), which are both below the acceptable 0.7 threshold. Data element validity testing of the measure is limited to one EHR system and was not completed across multiple vendors. Some testing data overlapped with the COVID-19 Public Health Emergency (PHE), raising concerns about representativeness.
- Implementation and Burden: The commenters emphasized that many systems lack the Natural Language Processing (NLP) tools required for eCQM implementation, which would add both cost and administrative burden. They noted that this complexity is particularly challenging for ancillary care clinicians in integrated systems, who may face added burden since hospital eCQMs track prophylaxis but not diagnostic timeliness.
- General Recommendations: The commenters recommended prioritizing decision-support tools over performance measures and urged CMS to further refine the measure specifications with additional stakeholder input before finalization. They also requested clarification on expectations for how diagnoses should be established within integrated health systems.

Response:

- Applicability and Scope: The measure is currently specified for primary care and intended for use in integrated health care settings. This measure will not be appropriate for some settings or locations; however, there may be potential to expand the measure to other settings in the future through the rulemaking process.
- Clinical Feasibility and Fairness: The 24-hour time frame was evaluated and deemed appropriate per the measure developer's technical expert panel and literature review. The measure would be optional to report, as clinicians have choice of which MIPS quality measures they choose to report. Therefore, clinicians will not be penalized for selecting another measure to report in the event clinician systems or resources are not adequate.
- Risk of Overuse/Defensive Medicine: Regarding the unintended consequence of overuse, the measure steward indicates that overuse of VTE diagnostic resources to avoid a high Diagnostic Delay of Venous Thromboembolism (DOVE) rate can be avoided in two ways: first by promoting the use of low-cost tools like D-dimer tests to rule out a VTE prior to ordering imaging, and second by using clinical decision support (CDS) tools built into the EHR.
- Measure Design Concerns and Measure Specifications: The measure developer assessed variation between sub-samples and found no significant differences by race, ethnicity, sex, insurance, and age. In literature, there are minimal to no differences in hospital length of stay (LOS) between men and women hospitalized for VTE, and no significant

[537] Office of the Surgeon General (US); National Heart, Lung, and Blood Institute (US). (2008). The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. Available from: https://www.ncbi.nlm.nih.gov/books/NBK44178/.

differences in mortality between men and women diagnosed with VTE.[538] [539] Although there are some disparities in the individuals who experience VTEs, there should not be disparities in the delayed diagnosis of VTE following the onset of symptoms noted by a clinician. The measure developer noted they are currently conducting a study to further investigate potential disparities. Regarding the list of symptoms included in the measure denominator, all of the symptoms included relate to either lower extremity venous thromboembolism (LE DVT) or pulmonary embolism (PE); however, most patients included in the eCQM measure developer testing data presented to primary care with a combination of signs/symptoms which appear within 30 days of the index primary care visit. There are no symptoms specific to VTE, and the measure developer selected the list of VTE-related signs/symptoms using a combination of literature review and qualitative methods (for example, interviews with clinicians with experience in treating VTE patients). Along with these signs/symptoms, this eCQM requires an ICD-10 diagnosis code, CPT imaging code, and RxNorm treatment code to accurately identify a patient with VTE, which adds specificity to denominator identification. The measure requires both VTE symptoms and a subsequent VTE diagnosis to be included in the denominator but does not specify or require any particular diagnostic testing. Additionally, if a patient is diagnosed during a primary care visit and goes elsewhere for imaging, they are not included in the denominator.

With regard to diagnosis and definition of the criteria for an eligible VTE event, the measure developer provided the following guidance:

- Patient is aged 18 years or older on the date of the primary care visit.
- The patient received a diagnosis of a lower limb VTE within 30 days of their primary care visit. For a patient to have a VTE diagnosis, they must have all of the following VTE-related codes within the same encounter:
    - ICD-10-CM (clinical modification) code for VTE.
    - CPT codes for an imaging scan for VTE linked to the same encounter as the ICD-10 CM code.
    - RxNorm order for therapeutic anticoagulants placed in the same encounter as the imaging scan.
- The patient must have no eligible VTE events within 6 months prior to the qualifying VTE event.

- Testing and Reliability Issues: Regarding testing concerns, the measure developer indicated additional data element testing is in progress for 3 EHR systems. While CMS does not have a minimum threshold for reliability, additional testing data provided by the measure developer shows higher reliability at the group level, reinforcing our rationale for implementation at the group level. While the measure developer acknowledges lower sample sizes due to part of data collection occurring during the COVID-19 PHE, there was sufficient data to complete testing, and the measure is CBE endorsed.
- Implementation and Burden: The measure developer noted the NLP is optional and is intended to be used in cases where symptoms are not otherwise documented using the codes in the value set. Free NLP license sources may be located online. The measure developer confirmed the NLP model has been tested successfully in different health systems.
- General Recommendations: The measure has been determined to be implementable as a MIPS eCQM at the group level as part of an integrated health system. The measure will undergo review as part of the annual update process to evaluate any potential or recommended changes to the measure specification, including additional guidance for implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32880 through 32881), we are finalizing the *Diagnostic Delay of Venous Thromboembolism in Primary Care* measure as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[538] Marshall, A. L., Bartley, A. C., Ashrani, A. A., Crusan, D. J., & Petterson, T. M. (2017). Sex-based Disparities in Venous Thromboembolism Outcomes: A National Inpatient Sample (NIS)-based analysis. *Vascular Medicine*, *22*(2),121-127. https://doi.org/10.1177/1358863X17693103.
[539] Mansour, S., Alotaibi, G., Wu, C., & McMurtry, M. S. (2017). Trends in Admission Rates and In-hospital Stay for Venous Thromboembolism. *Thrombosis Research*, *156*, 149–154. https://doi.org/10.1016/j.thromres.2017.06.012.

A.4. Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	515
Description:	Percentage of adult patients with risk factors for type 2 diabetes who are due for glycemic screening for whom the screening process was completed during the measurement period.
Measure Steward:	American Medical Association
Numerator:	Patients who had a glycemic screening test performed during the measurement period.
Denominator:	All patients with at least two outpatient clinical encounters or one preventive clinical encounter during the measurement period who have the following risk factors for type 2 diabetes: - Most recent BMI ≥25 kg/m2 (BMI ≥23 kg/m2 for Asian patients) during measurement period, AND - Age 35-70 at start of measurement period.
Exclusions:	- Patient's pregnancy overlaps measurement period. - Patient with diagnosis of advanced illness or limited life expectancy overlaps measurement period. - Patient with diagnosis of diabetes overlaps 2-year look-back period. - Patient with diagnosis of prediabetes overlaps 2-year look-back period. - Patient with glycemic screening performed during 2-year look-back period.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	eCQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this eCQM because it captures a critical process to identify patients with prediabetes who may benefit from interventions to prevent type 2 diabetes and patients with undiagnosed type 2 diabetes. Regular glycemic screening is a critical first step to identifying patients with prediabetes and helping patients avoid the disability and costs associated with progression to type 2 diabetes. The Centers for Disease Control and Prevention (CDC) estimates that approximately 98 million American adults have prediabetes.[540] They note that more than 80 percent of adults with prediabetes are not aware that they have the condition.[541] This measure aligns with current United States Preventive Services Task Force (USPSTF) clinical guidelines for pre-diabetes screening, which recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who are overweight or have obesity.[542] An estimated 13 percent of all U.S. adults (18 years or older) have diabetes, and 34.5 percent meet criteria for prediabetes. Diabetes is the leading cause of kidney failure and new cases of blindness among adults in the U.S. It is also associated with increased risks of cardiovascular disease, nonalcoholic fatty liver disease, and nonalcoholic steatohepatitis and was estimated to be the seventh leading cause of death in the U.S. in 2017. Screening asymptomatic adults for prediabetes and type 2 diabetes may allow earlier detection, diagnosis, and treatment, with the goal of improving health outcomes.[543] This fully tested and developed measure will fill a gap in MIPS, which does not have any related measures that examine the rate of screening for abnormal glucose metabolism in patients at risk for diabetes. This measure will ensure timely identification of patients with prediabetes for early intervention and may be a potential future addition to the Value in Primary Care MVP. The PRMR Clinician Recommendation Committee recommended this measure. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. As mentioned previously, this measure aligns with USPSTF evidence-based clinical guidelines.[544] The measure was found during the MERIT submission process to be feasible as an eCQM at the clinician level with high levels of agreement for data element testing of a similar non-MIPS eCQM. Additionally, measure testing demonstrates adequate measure score reliability, high face validity, and median performance scores that indicate significant room for improvement among clinicians. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes measure. A commenter noted that the measure aligns with the Administration's focus on disease prevention and empowering individuals to make lifestyle changes that support overall wellness. The commenters emphasized that implementing measures to facilitate diabetes screening would reinforce the CDC National Diabetes Prevention Program, which already requires grantees under its cooperative agreement to ensure physicians screen and refer patients to community-based lifestyle programs. Finalizing the measure for use in MIPS would therefore align CMS, CDC, and broader prevention efforts. The measure also received unanimous support during the Pre-Rulemaking Measure Review process. Commenters looked forward to continuing to educate and increase awareness about the Medicare Diabetes Prevention Program as an evidence-based treatment for patients with prediabetes. Another commenter supported this new measure, stating that it reflects ongoing movement toward interoperability and more timely performance data.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: A commenter supported adding the measure as an optional MIPS measure and provided recommendations for improvement. They urged CMS and the measure steward to ensure flexibility in test selection based on clinical appropriateness, avoid incentivizing unnecessary or overly frequent screening in low-risk patients, and provide clear guidance on coding and documentation to reduce administrative burden. The commenter also requested that the measure steward seek CBE endorsement. Additional recommendations included revising the measure to accept data from Continuous Glucose Monitors (including a glucose management indicator), incorporating stratification to assess disparities in screening rates by race, ethnicity, and

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[540] Centers for Disease Control and Prevention (CDC). (2022). National Diabetes Statistics Report website. https://www.cdc.gov/diabetes/php/data-research/index.html#:~:text=Prevalence%20of%20prediabetes%20among%20adults%201%20An%20estimated,professional%20that%20they%20had%20this%20condition%20%28Table%204%29.

[541] See footnote CDC, 2022.

[542] US Preventive Services Task Force (USPSTF), Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., Donahue, K. E., Doubeni, C. A., Krist, A. H., Kubik, M., Li, L., Ogedegbe, G., Owens, D. K., Pbert, L., Silverstein, M., Stevermer, J., Tseng, C. W., & Wong, J. B. (2021). Screening for Prediabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement. *JAMA*, *326*(8), 736–743. https://doi.org/10.1001/jama.2021.12531.

[543] See footnote USPSTF et al., 2021.

[544] See footnote USPSTF et al., 2021.

socioeconomic status, clarifying the appropriate rescreening interval for patients with normal results, and ensuring the measure does not penalize practices that emphasize shared decision-making and individualized care plans.

Response: The measure is currently tested and specified to utilize fasting plasma glucose, glucose tolerance test or hemoglobin A1c; however, we thank the commenters for these suggestions and encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years. While we agree CBE endorsement is preferred, this measure should nonetheless be added to MIPS as it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. The measure is based on current clinical guidelines for pre-diabetes screening for patients who are overweight or obese as determined by their Body Mass Index (BMI).[545] The clinical guideline recommends glycemic screening in the denominator population because they determined that there is high certainty that the net benefit of screening is moderate or there is moderate certainty that the net benefit is moderate to substantial. Therefore, the risk of unintended consequences from implementing this measure is low. During measure testing the developer determined the measure is not recommended to be stratified. With regards to screening interval, there are exclusions to account for the patients for whom glucose metabolism screening is not appropriate and will discourage over screening, and while there is not an exclusion for patient refusal, this should affect all clinicians reporting the measure equally and all MIPS eligible clinicians have choice in what measures they choose to report.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32882 through 32883), we are finalizing the *Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes* measure as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[545] See footnote USPSTF et al., 2021.

A.5. Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	516
Description:	Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.
Measure Steward:	American Gastroenterological Association
Numerator:	All patients aged greater than or equal to 18 years at the time of the eligible encounter with an eligible encounter and positive/detectable HCV RNA test result in the denominator identification period who have a subsequent negative/undetectable HCV RNA test result 20 weeks to 12 months after first positive/detectable HCV RNA test result identified in the denominator identification period.
Denominator:	All patients aged >= 18 years with an active Hepatitis C Virus diagnosis at the time of the eligible encounter within the denominator identification period with a positive/detectable Hepatitis C Virus or qualitative RNA Test Result
Exclusions:	Patients receiving hospice or palliative care or who died during the measurement period.
Measure Type:	Outcome
High Priority Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We proposed this outcome measure because achieving SVR is the first step toward reducing future HCV morbidity and mortality. Once achieved, SVR is associated with long-term clearance of HCV infection, which is regarded as a virologic "cure," as well as with improved morbidity and mortality. Patients who achieve SVR usually have an improvement in liver histology and clinical outcomes. This measure is supported by American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD-IDSA) HCV Guidance Panel clinical guidelines that strongly recommend universal direct-acting antiviral treatment for all patients with acute or chronic HCV infections.[546] Additional evidence from cohort studies evaluated the association between SVR after antiviral therapy and mortality or complications of chronic HCV infection. SVR was associated with decreased risk for all-cause mortality, liver-related mortality, and other complications of end-stage liver disease versus no SVR.[547] This measure could be added to the Gastroenterology Care and Prevention and Treatment of Infectious Disorders Including Hepatitis and HIV MVPs in the future and will fill a current quality measure inventory gap within the Hepatitis C clinical topic area. In addition, it will provide a specialty specific outcome measure for the MIPS Gastroenterology and Infectious Disease specialty sets under Tables B.14 and B.18 of this Appendix. The PRMR Clinician Recommendation Committee recommended this measure without conditions. Testing was completed at the clinician level with a small sample size due to accessibility to data. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. As mentioned previously, this measure aligns with AASLD-IDSA HCV Guidance Panel evidence-based clinical guidelines. The measure was found during the MERIT submission process to be feasible at the clinician level and data element testing was completed showing exact data element agreement values of 52 percent, indicating moderate reliability. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Hepatitis C Virus (HCV): Sustained Virological Response (SVR) Quality Measure, emphasizing its importance in advancing national HCV elimination goals. They explained that SVR, defined as undetectable HCV RNA 12 weeks after treatment, is the gold standard for determining cure and serves as a meaningful outcome measure. With the availability of point-of-care HCV RNA testing, pan-genotypic antivirals, and cure rates exceeding 95 percent, the measure supports single-visit test-and-treat strategies, improves linkage to care and treatment rates, and helps identify gaps in the care continuum. Commenters also highlighted that the measure promotes evidence-based practice improvements, demonstrates the value of infectious diseases physicians, and provides key data on both clinical and economic impacts of HCV care. A commenter further noted that this measure is included in the CQMC HIV/Hepatitis C core measure set.

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[546] Bhattacharya, D., Aronsohn, A., Price, J., Lo Re, V., & AASLD-IDSA HCV Guidance Panel (2023). Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, ciad319. Advance online publication. https://doi.org/10.1093/cid/ciad319.

[547] Chou, R., Dana, T., Fu, R., Zakher, B., Wagner, J., Ramirez, S., Grusing, S., & Jou, J. H. (2020). Screening for Hepatitis C Virus Infection in Adolescents and Adults: A Systematic Review Update for the U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality (US).

Another commenter indicated finalization of this measure could further motivate Medicare Advantage plans to include similar performance measures to have a standard set of reportable metrics to inform disease detection and elimination efforts.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: A commenter supported the new measure, noting that while direct-acting antivirals (DAAs) are highly effective at achieving SVR, they are not 100 percent effective and may be slightly less effective in patients with HIV or Hepatitis B (HBV) coinfection. The commenter explained that HBV is generally treated before HCV due to the risk of flare. The commenter pointed out that although the measure excludes patients who do not undergo repeat HCV DNA testing for reasons such as concomitant infection, it does not exclude individuals with concomitant infection from the denominator. The commenter recommended that the measure steward consider adding exceptions for these patients as well as for patients who decline treatment.

Response: We thank the commenter for supporting this new measure and for the exclusion suggestions. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Patient refusal of treatment typically affects all MIPS eligible clinicians who report the measure equally, and we would expect clinicians to take the opportunity to educate patients on appropriate treatment for this chronic condition.

Comment: A commenter supported the goal of increasing Hepatitis C treatment but raised concerns that an SVR-focused quality measure could lead clinicians to prioritize patients more likely to return for post-SVR testing while excluding marginalized populations, such as people who use drugs or are experiencing homelessness. The commenter stated that an SVR measure would not accurately capture cure rates, as many cured patients may not undergo SVR testing. The commenter recommended instead using measure Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation to assess Hepatitis C-related care quality, which would better promote equitable care.

Response: We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years as some concerns may be addressed with a denominator exception for lack of follow up. However, we would expect clinicians to take the opportunity to educate patients on appropriate treatment and follow-up for this chronic condition. Clinicians also have choice in which measures they choose to report in MIPS. With regards to accurate capture of cure rates, the patient would require a positive Hepatitis C Virus Quantitative or Qualitative RNA Test Result to be included in the denominator and measure testing indicated high face validity and adequate measure score reliability.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32884), we are finalizing the *Hepatitis C Virus (HCV): Sustained Virological Response (SVR)* measure as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

Table Group B: Modifications to Previously Finalized Specialty Measure Sets Finalized for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

In the CY 2026 PFS proposed rule (90 FR 32885), we proposed modifying the previously finalized specialty measure sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). The Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. Additionally, eCQMs that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Under § 414.1305, as finalized in this final rule under Section IV.A.4.f(1)(b), a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid quality measure.[548] Further details of these types of measures may be found in the CMS Measures Management System Hub (https://mmshub.cms.gov/).

NOTE:

- Updates to measure titles and/or measure descriptions under Table Group B in this final rule may or may not be considered substantive in nature, therefore may not be proposed or updated under Table Group D. If the change was considered substantive in nature, it was finalized under Table Group D.
- Under Table Group B, we responded to comments related to new measures that were proposed for addition to measure sets, as well as measures proposed for removal. Any comments received on previously finalized measures that have no substantive changes are out of scope and not included in this final rule. Commenters who requested additions or removals of quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.
- For each specialty set, measures in the Previously Finalized tables and any new measures finalized under applicable Addition tables will be available for reporting in CY 2026.

We requested comments on proposed measure additions and/or proposed measure removals under applicable specialty sets in Table Group B of this Appendix. Previously finalized measures that had no substantive changes were not open for comment under the proposed rule.

The following specialty sets were not open for comment as they had no proposed modifications (addition and/or removal tables), and no proposed substantive changes to previously finalized measures for the CY 2026 performance period/2028 MIPS payment year: Electrophysiology Cardiac Specialist, Dentistry, Diagnostic Radiology, and Pathology.

The following specialty sets had no proposed modifications but had proposed substantive changes to previously finalized measures that were open for comment under Table Group D of this Appendix: Hospitalists, Radiation Oncology, and Optometry.

The remaining specialty sets had proposed modifications and were open for comment.

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[548] Note that under Section IV.A.4.f.(1)(b) of this final rule, the term "health equity" is finalized for removal from the definition of a high priority measure.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS314v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
§ ! (Efficiency)	N/A / N/A	340	CMS1157v2	eCQM, MIPS CQM	Process	**HIV Annual Retention in Care:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the performance period.	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32888), we are finalizing the above measure(s) for removal from the *Allergy/Immunology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQM	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQM	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQM	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQM	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE ANESTHESIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	424	N/A	MIPS CQM	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32890), we are finalizing the above measure(s) for removal from the *Anesthesiology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	2152/ N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE AUDIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32893), we are finalizing the above measure(s) for removal from the *Audiology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS135v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS145v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS144v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy**: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Inter-mediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQM	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS347v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR; •Patients aged 40 to 75 years with a diagnosis of diabetes; OR; •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • High Intensity Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
! (Outcome)	3665/ N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CARDIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	322	N/A	MIPS CQM	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support removal of measure Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients but acknowledged CMS' rationale for proposing removal due to topped-out performance. They cautioned against eliminating one of the few cardiology-specific efficiency measures without a replacement, stressing that cardiac imaging remains an important policy and practice issue and that the measure serves as a signal

of appropriate use. While not opposing retirement, the commenter urged CMS to pair it with a broader imaging overuse measure covering echocardiography, nuclear stress testing, and coronary CTA in clearly low-value scenarios. They further recommended refining specifications to capture clinical purpose across settings, leveraging EHR-based clinical decision support to reduce inappropriate testing, granting Improvement Activity credit for CDS use and feedback to ordering clinicians, and using claims data to identify high-outlier sites for targeted outreach.

Response: We thank the commenter for their feedback. As discussed under Table C.4 of this Appendix, measure Q322 is extremely topped out, which demonstrates it has become a standard of care. We acknowledge that removal of this measure decreases the number of available measures for this specialty; however, there are policies in place, such as Eligible Measure Applicability (EMA) and denominator reduction to account for this when working to meet MIPS quality performance category requirements. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement and focus on specialty sets on areas with greater room for improvement to drive more meaningful gains in quality of care. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2025 Benchmark File.

We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

Comment: Regarding measure Q487: Social Drivers of Health, a commenter stated that many cardiology practices, particularly in ACOs or integrated care models, are beginning to embed social determinants of health screening into routine workflows. ACOs operate under value-based payment arrangements, which incentivizes them to improve patient outcomes and control costs. Removing this measure may discourage continued advancement in this area. If CMS proceeds with removal from the cardiology set, the commenter urged its retention in primary care-aligned or multispecialty MVPs to ensure continued attention to social risk factors to improve outcomes across specialties.

Response: As discussed under Table C.8 of this Appendix, measure Q487 is a process measure that no longer addresses a priority area and will no longer be considered a high-priority measure. As explained in the removal rationale, removing this measure aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32899), we are finalizing the above measure(s) for removal from the *Cardiology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no proposed changes.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQM	Outcome	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQM	Outcome	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
	N/A / N/A	496	N/A	MIPS CQM	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE CERTIFIED NURSE MIDWIFE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE CERTIFIED NURSE MIDWIFE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32903 through 32904), we are finalizing the above measure(s) for removal from the *Certified Nurse Midwife Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CHIROPRACTIC MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32907), we are finalizing the above measure(s) for removal from the *Chiropractic Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
! (Opioid)	N/A / N/A	305	CMS137v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0710 / 0710e	370	CMS159v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS177v14	eCQM	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed including this measure in the Clinical Social Work specialty set as we agreed with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[549] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure will help fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[550] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and will promote more universal adoption of best practices to support shared decision making.[551] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family

[549] Frosch, D. L., May, S. G., Rendle, K. A., Tietbohl, C., & Elwyn, G. (2012). Authoritarian Physicians and Patients' Fear of Being Labeled 'Difficult' Among Key Obstacles to Shared Decision Making. Health Affairs (Project Hope), 31(5), 1030–1038. https://doi.org/10.1377/hlthaff.2011.0576.

[550] Teno, J. M., Clarridge, B. R., Casey, V., Welch, L. C., Wetle, T., Shield, R., & Mor, V. (2004). Family Perspectives on End-of-Life Care at the Last Place of Care. JAMA, 291(1), 88–93. https://doi.org/10.1001/jama.291.1.88.

[551] National Consensus Project for Quality Palliative Care. (2018). Clinical Practice Guidelines for Quality Palliative Care, 4th edition. https://www.nationalcoalitionhpc.org/ncp.

B.7. Clinical Social Work

MEASURES FINALIZED FOR ADDITION TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								members or other caregivers.[552] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported adding measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this specialty set. One of the commenters recommended CMS consider adding this measure to all specialty sets.

Response: We thank the commenters for supporting the addition of this measure to the Clinical Social Worker specialty set. We encourage the commenter to request this measure be added to other specialty sets through the Solicitation for Specialty Sets process.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32913 through 32914), we are finalizing the above measure(s) for addition to the *Clinical Social Worker Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CLINICAL SOCIAL WORK SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

[552] Meier, D. E. (2011). Increased Access to Palliative Care and Hospice Services: Opportunities to Improve Value in Health Care. The Milbank Quarterly, 89(3), 343–380. https://doi.org/10.1111/j.1468-0009.2011.00632.x.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE CLINICAL SOCIAL WORK SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support the proposed removals of measures Q487: Screening for Social Drivers of Health and Q498: Connection to Community Service Provider from this specialty set. The commenter stated that screening for social drivers of health is essential to identify nonmedical factors—such as housing, food, and transportation—that significantly affect mental health and substance use, and highlighted that without these measures, accountability for addressing patient needs would be reduced. The commenter recommended that if CMS proceeds with removal, alternative approaches should leverage existing data sources and workflows to avoid added administrative burden.

Response: As discussed under Tables C.8 and C.9 of this Appendix, measures Q487 and Q498 are process measures that no longer address a priority area and will no longer be considered high-priority measures. As explained in the removal rationale, removing these measures aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32914), we are finalizing the above measure(s) for removal from the *Clinical Social Work Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no proposed changes.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	378	CMS 75v14	eCQM	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
	N/A / N/A	379	CMS 74v15	eCQM	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A/ N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	410	N/A	MIPS CQM	Intermediate Outcome	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Outcome)	N/A / N/A	485	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of three or more points at a follow up visit.	American Academy of Dermatology
! (Outcome)	N/A / N/A	486	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	509	N/A	MIPS CQM	Process	**Melanoma: Tracking and Evaluation of Recurrence:** Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II in the past 5 years in which the operating provider examines and/or diagnoses the patient for recurrence of melanoma.	American Academy of Dermatology

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DERMATOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32918), we are finalizing the above measure(s) for removal from the *Dermatology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no proposed changes.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQM	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQM	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3633e, 3662e / N/A	494	CMS1056v3	eCQM	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of patients with CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This measure is not telehealth eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069/ N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQM	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
! (Efficiency)	N/A / N/A	416	N/A	MIPS CQM	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE EMERENCY MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32924), we are finalizing the above measure(s) for removal from the *Emergency Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS122v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	236	CMS16 5v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS347v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
	N/A / N/A	462	CMS645v9	eCQM	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS95 1v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ENDOCRINOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32929), we are finalizing the above measure(s) for removal from the *Endocrinology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS1 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS1 35v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS1 45v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0083 / 0083e	008	CMS1 44v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
	N/A / N/A	009	CMS1 28v14	eCQM	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0069 / N/A	065	CMS1 54v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS1 46v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	236	CMS1 65v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS1 56v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
! (Opioid)	N/A / N/A	305	CMS1 37v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS1 24v14	eCQM	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS1 39v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement /Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS314v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS159v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS90v15	eCQM	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQM	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* §	N/A / N/A	394	N/A	MIPS CQM	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age-appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years who have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQM	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS347v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • High Intensity Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS7 71v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The Larry Greem Center
*	N/A / N/A	488	CMS9 51v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

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MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

MEASURES FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / 3749e	514	CMS1173v1	eCQM	Intermediate Outcome	**Diagnostic Delay of Venous Thromboembolism in Primary Care:** Percentage of episodes for patients 18 years of age and older with documented Venous Thromboembolism (VTE) symptoms in the primary care setting and who had a diagnosis of VTE that occurs >24 hours and within 30 days following the index primary care visit where symptoms for the VTE were first present.	Brigham and Women's Hospital	We proposed including this measure in the Family Medicine specialty set as this measure is clinically relevant to this clinician type. Family physicians provide preventive care, diagnose and treat acute and chronic illness, and manage chronic diseases.[553] Venous thromboembolism (VTE) is a serious and preventable health problem that requires timely diagnosis and treatment in order to reduce morbidity and mortality.[554] Due to this specialist's broad scope of care, patients often present to them first with non-specific symptoms prior to being diagnosed.[555] This measure is currently specified for primary care and intended to improve early recognition which can reduce adverse patient outcomes. The measure addresses a gap in MIPS for the treatment of patients with venous thromboembolism, specifically the commonly missed or delayed diagnosis in primary care requiring timely and adequate treatment. Including this measure in this specialty set can potentially improve diagnostic performance leading to a reduction in patient complications, decreased patient mortality and morbidity, and lowered health care costs.[556] Enhancing the family medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of VTE diagnosis and treatment. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this

[553] The American Academy of Family Physicians (AAFP). Primary Care website. https://www.aafp.org/about/policies/all/primary-care.html#:~:text=Primary%20care%20physicians%20specifically%20are,a%20partner%20in%20health%20care.

[554] See footnote Tagalakis et al., 2013.

[555] See footnote Tagalakis et al., 2013.

[556] See footnote Liederman et al., 2020.

MEASURES FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								specialty measure set.
	N/A / N/A	515	CM S11 54v1	eCQM	Process	**Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes:** Percentage of adult patients with risk factors for type 2 diabetes who are due for glycemic screening for whom the screening process was completed during the measurement period.	American Medical Association	We proposed including this measure in the Family Medicine specialty set as this measure is clinically relevant to this clinician type. Family medicine clinicians are likely the most frequent point of contact for many patients as their scope of care is extensive and inclusive of many different patient populations and conditions. This measure focuses on patients with risk factors for developing type 2 diabetes and enhances early detection and prevention of diabetes. Regular glycemic screening is an important first step to identifying patients with prediabetes and help patients avoid the disability and the cost associated with progression to type 2 diabetes.[557] This measure aligns with national USPSTF guidelines and recommendations of screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity.[558] Nearly 98 million people have prediabetes, but more than 8 in 10 adults do not know they have it[559] reinforcing the importance of identifying patients with prediabetes and identifying patients with undiagnosed type 2 diabetes. Enhancing the family medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of glucose screening in patients at risk for diabetes. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[557] Kushner, P. R., Cavender, M. A., & Mende, C. W. (2022). Role of Primary Care Clinicians in the Management of Patients With Type 2 Diabetes and Cardiorenal Diseases. Clinical Diabetes: A Publication of the American Diabetes Association, 40(4), 401–412. https://doi.org/10.2337/cd21-0119.

[558] See footnote USPSTF et al., 2021.

[559] See footnote CDC, 2022.

MEASURES FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	516	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.	American Gastroenterological Association	We proposed including this measure in the Family Medicine specialty set as this measure is clinically relevant to this clinician type. Family medicine clinicians are likely the most frequent point of contact for many patients as their scope of care is extensive and inclusive of many different patient populations. Family physicians diagnose and treat acute illnesses, provide preventive care, and manage chronic illness.[560] Due to their broad scope of care, this specialty may treat patients with active hepatitis C (HCV) and assist in managing the disease. This quality measure aligns with clinical guidelines of the U.S. Preventive Services Task Force (USPSTF) and achieving Sustained Virological Response (SVR) is the first step toward reducing future HCV morbidity and mortality.[561] The American Academy of Family Physicians have advocated for increased management of HCV within primary care along with family medicine residency program directors working over the past 5 years to build capacity for HCV treatment within the specialty by training future generations of family medicine physicians.[562] Enhancing the family medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of proper management of patients with HCV. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[560] AAFP. Primary Care website. https://www.aafp.org/about/policies/all/primary-care.html#:~:text=Primary%20care%20physicians%20specifically%20are,a%20partner%20in%20health%20care
[561] USPSTF. (2020). Final Recommendation Statement: Hepatitis C Virus Infection in Adolescents and Adults: Screening. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening#bootstrap-panel--6.
[562] Simoncini, G. M., & Koren, D. E. (2019). Hepatitis C Update and Expanding the Role of Primary Care. Journal of the American Board of Family Medicine: JABFM, 32(3), 428–430. https://doi.org/10.3122/jabfm.2019.03.180286.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A commenter supported adding the new Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes as an optional measure. This commenter did not support adding the new Diagnostic Delay of Venous Thromboembolism in Primary Care measure to this specialty set as currently specified. See complete comments under Table Group A (Tables A.3 and A.4) of this Appendix.

Response: We appreciate the commenter's feedback on adding new measures to the Family Medicine specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32946 through 32950), we are finalizing the above measure(s) for addition to the *Family Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	443	N/A	MIPS CQM	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the removal of measures Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females; Q487: Screening for Social Drivers of Health; Q498: Connection to Community Service Provider; and Q508: Adult COVID-19 Vaccination Status from this specialty set. The commenter looks forward to working with CMS on its future plans to address health disparities through other mechanisms.

Response: We thank the commenter for supporting the removal of these four measures from the Family Medicine specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32951), we are finalizing the above measure(s) for removal from the *Family Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	NA / N/A	275	N/A	MIPS CQM	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS22v 14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50v 14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQM	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.14. Gastroenterology

MEASURES FINALIZED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	516	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.		We proposed including this measure in the Gastroenterology specialty set as we agreed with interested parties that this measure is clinically relevant to this specialty type. The measure is stewarded by the American Gastroenterological Association and its addition to this specialty set will be feasible given the high rates that this specialty assesses, treats, and manages diseases that affect the organs in the digestive system, including the liver.[563] Enhancing the gastroenterology related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within this specialty set and its addition will elevate the importance of providing standard care to patients living with the hepatitis C (HCV liver disease.[564] This measure is based on evidence-based guidance for HCV management and will help ensure patients with HCV are receiving the best possible care, thus improving patient safety, and reducing future HCV morbidity and mortality.[565] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (90 FR 32955), we are finalizing the above measure(s) for addition to the *Gastroenterology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[563] See footnote Bhattacharya et al., 2023.
[564] See footnote Bhattacharya et al., 2023.
[565] See footnote Bhattacharya et al., 2023.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GASTROENTEROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	185	N/A	MIPS CQM	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32956), we are finalizing the above measure(s) for removal from the *Gastroenterology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQM	Outcome	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GENERAL SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	264	N/A	MIPS CQM	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32959), we are finalizing the above measure(s) for removal from the *General Surgery Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022 / N/A	238	CMS156 v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149 v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
! (Patient Safety)	0101 / N/A	318	CMS139 v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159 v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Outcome)	N/A / N/A	476	CMS771 v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS951 v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within the 12-month measurement period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.16. Geriatrics

MEASURES FINALIZED FOR ADDITION TO THE GERIATRICS SPECIALTY SET								
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Inclusion

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
§	N/A / N/A	226	CM S13 8v14	Medicare Part B Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We proposed including this measure in the Geriatrics specialty set as this measure is clinically relevant to this clinician type. Tobacco use is the leading preventable cause of disease, disability, and death in the U.S. cigarette smoking results in more than 480,000 premature deaths each year and accounts for approximately 1 in every five deaths.[566] There is an increase in smoking-related deaths in people over the age of 60 years, where this population's smoking-related mortality is largely caused by lung cancer.[567] Smoking can also reduce efficacy of vaccines and increase the risk for infections in the older patient population.[568] Older adults who quit smoking experience positive effects on their health such as reduced cognitive decline and better quality of life.[569] Due to the harmful effect tobacco use can have on patients' health, clinicians should engage with their patients to screen for tobacco use and, if positive, provide tobacco cessation counseling annually.[570] This measure was previously included in this specialty set and removed beginning with the CY 2024 performance period/2026 MIPS payment year due to being included as a component of the previously finalized MIPS quality measure 497: Preventive Care and Wellness (composite) making them duplicative. However, we agreed with interested parties' feedback that not all components of measure Q497 apply to this patient population, most specifically Body Mass Index (BMI). We proposed adding this component measure to this specialty set due to the importance of the clinical concept to this specialty where the complete composite measure will not be applicable. Enhancing the geriatrics related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will

[566] CDC. (2024). Current Cigarette Smoking Among Adults in the United States website. https://www.cdc.gov/tobacco/php/data-statistics/adult-data-cigarettes/index.html.
[567] Godoy, P., Castilla, J., Soldevila, N., Mayoral, J. M., Toledo, D., Martín, V., Astray, J., Egurrola, M., Morales-Suarez-Varela, M., Domínguez, A., & CIBERESP Cases and Controls in Pandemic Influenza Working Group, Spain* (2018). Smoking May Increase the Risk of Influenza Hospitalization and Reduce Influenza Vaccine Effectiveness in the Elderly. *European Journal of Public Health*, *28*(1), 150–155. https://doi.org/10.1093/eurpub/ckx130.
[568] See footnote Godoy et al., 2018.
[569] Kivipelto, M., Mangialasche, F., & Ngandu, T. (2018). Lifestyle Interventions to Prevent Cognitive Impairment, Dementia and Alzheimer Disease. *Nature Reviews. Neurology*, *14*(11), 653–666. https://doi.org/10.1038/s41582-018-0070-3.
[570] See footnote CDC, 2024.

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								elevate the importance of preventive care and screening for tobacco use.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A commenter supported adding measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention to this specialty set given tobacco's impact on cancer, complications, and outcomes. The commenter noted importance of access to cessation resources and barriers in low-income and rural areas where resources are limited or costly, making cessation harder for those needing product support.

Response: We thank the commenter for supporting the addition of this measure to the Geriatrics specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32964 through 32965), we are finalizing the above measure(s) for addition to the *Geriatrics Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GERIATRICS SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare & Medicaid Services	We proposed removing this measure from the Geriatrics specialty set as we agreed with interested parties' feedback that the age and sex appropriate preventive screenings included in all the components of this composite measure are not applicable to this patient population. Specifically, we agreed with their concern that the parameters within this composite measure's Body Mass Index (BMI) component may not be appropriate for use in older adults.[571] Observational studies suggest that older adults with BMI in the 27-32 range are at lowest risk of adverse outcomes.[572] Additionally, in older adults a higher BMI classification may be associated with lower mortality risks, demonstrating the potential need for age-specific BMI cut-points in older adults.[573]

[571] CDC. Current Cigarette Smoking Among Adults in the United States website. https://www.cdc.gov/tobacco/php/data-statistics/adult-data-cigarettes/index.html.
[572] Javed, A. A., Aljied, R., Allison, D. J., Anderson, L. N., Ma, J., & Raina, P. (2020). Body Mass Index and All-Cause Mortality in Older Adults: A scoping Review of Observational Studies. Obesity Reviews: An Official Journal of the International Association for the Study of Obesity, 21(8), e13035. https://doi.org/10.1111/obr.13035.
[573] See footnote Javed et al., 2020.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GERIATRICS SPECIALTY SET							
Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our response.

Comment: A commenter supported removing measure Q497: Preventive Care and Wellness (composite) from this specialty set. They agreed that clinicians should actively address preventive care and wellness to support overall patient health but stated that a composite measure may not effectively encourage adherence to the individual preventive care activities it covers, or account for the unique circumstances of older adults that may make certain preventive measures inappropriate.

Response: We thank the commenter for supporting the removal of measure Q497 from the Geriatrics specialty set.

Comment: A commenter opposed removal of measures from this specialty set. The commenter stated that measure Q487: Screening for Social Drivers of Health is critical to patient well-being and supports a comprehensive approach to disease prevention and health promotion. The commenter opposed removal of measure Q498: Connection to Community Service Provider measure and recommended keeping the measure and ensuring interventions are evidence-based and tracked to improve access. The commenter opposed removal of measure Q508: Adult COVID-19 Vaccination Status and noted recent FDA approval of updated vaccines. The commenter also recommended annual reevaluation and updates as new evidence emerges.

Response: As discussed under Tables C.8, C.9, and C.10 of this Appendix, measures Q487, Q498, and Q508 are process measures that no longer address a priority area and will no longer be considered high-priority measures. As explained in the removal rationale, removing these measures aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 32966 through 32967), we are finalizing the above measure(s) for removal from the *Geriatrics Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS135v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0083 / 0083e	008	CMS144v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through 3 days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / 3755e	205	CMS1188v3	eCQM, MIPS CQM	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS117v14	eCQM	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
§ ! (Outcome)	NA / N/A	338	CMS314v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	CMS1157v2	eCQM, MIPS CQM	Process	**HIV Annual Retention in Care:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the performance period.	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQM	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	394	N/A	MIPS CQM	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	516	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.	American Gastroenterological Association	We proposed including this measure in the Infectious Disease specialty set as this measure is clinically relevant to this specialty type. Clinicians in this specialty are skilled in the diagnosis, treatment, and management of acute and chronic infections. Enhancing the infectious disease related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within this specialty set and its addition will elevate the importance of providing standard care to patients living with hepatitis C (HCV) liver disease.[574] This measure is based on evidence-based guidance for HCV management and will help ensure patients with HCV are receiving the best possible care, thus improving patient safety, and reducing future HCV morbidity and mortality.[575] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (90 FR 32973), we are finalizing the above measure(s) for addition to the *Infectious Disease Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[574] See footnote Bhattacharya et al., 2023.
[575] See footnote Bhattacharya et al., 2023.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INFECTIOUS DISEASE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32974), we are finalizing the above measure(s) for removal from the *Infectious Disease Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

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In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS122v 14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS135v 14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS145v 14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0083 / 0083e	008	CMS144 v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
	N/A / N/A	009	CMS128 v14	eCQM	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

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Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 5	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	236	CMS165 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156 v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS137 v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124 v14	eCQM	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139 v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS314 v3	eCQM, MIPS CQM	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS159 v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS90v 15	eCQM	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years who have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQM	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

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Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS347 v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

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Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • High Intensity Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS349 v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771 v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

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Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items - to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The Larry Green Center
*	N/A / N/A	488	CMS951 v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)

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Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	515	CM S11 54v1	eCQM	Process	**Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes:** Percentage of adult patients with risk factors for type 2 diabetes who are due for glycemic screening for whom the screening process was completed during the measurement period.	American Medical Association	We proposed including this measure in the Internal Medicine specialty set as this measure is clinically relevant to this clinician type. Internal medicine clinicians treat a broad and comprehensive scope of illnesses affecting adults, specializing in health promotion, disease prevention, and diagnosis and treatment of chronic illness, including patients with diabetes.[576] Due to their broad scope of care, this specialty can be crucial in early detection of patients at risk for developing type 2 diabetes.[577] Regular glycemic screening and timely identification of prediabetics helps patients avoid the disability and the cost associated with progression to type 2 diabetes.[578] This measure aligns with national USPSTF evidence-based guidelines and recommendations of screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity.[579] Nearly 98 million people have prediabetes, but more than 8 in 10 adults do not know they have it[580] reinforcing the importance of identifying patients with prediabetes and identifying patients with undiagnosed type 2 diabetes. Enhancing the internal medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of glucose screening in patients at risk for diabetes. The measure being added to this specialty set was contingent on the inclusion of

[576] American College of Physicians (ACP). The Cornerstone of Comprehensive Health Care website. https://www.acponline.org/about-acp/about-internal-medicine/the-cornerstone-of-comprehensive-health-care.
[577] ACP. (2025). What is an Internal Medicine Physician, or Internist? https://www.acponline.org/about-acp/about-internal-medicine/what-is-an-internal-medicine-physician-or-internist.
[578] See footnote Kushner et al., 2022.
[579] See footnote USPSTF et al., 2021.
[580] See footnote CDC, 2022.

MEASURES FINALIZED FOR ADDITION TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
! (Outcome)	N/A / N/A	516	N/A	MIPS CQM	Outcome	**Hepatitis C Virus (HCV): Sustained Virological Response (SVR):** Percentage of patients aged greater than or equal to 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.	American Gastroenterological Association	We proposed including this measure in the Internal Medicine specialty set as this measure is clinically relevant to this clinician type. Internal medicine clinicians are likely the most frequent point of contact for many patients as their scope of care is extensive and inclusive of many different patient populations. Internal medicine clinicians diagnose and treat acute illness, provide preventive care, and manage chronic illness.[581] Due to their broad scope of care, this specialty may treat patients with active hepatitis C (HCV) and assist in managing the disease. This quality measure aligns with clinical guidelines of the USPSTF and achieving Sustained Virological Response (SVR) is the first step toward reducing future HCV morbidity and mortality.[582] Enhancing the internal medicine related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of proper management of patients with HCV. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized

[581] See footnote ACP, 2025.
[582] See footnote USPSTF, 2020.

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								for inclusion within this specialty measure set.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (90 FR 32991 through 32993), we are finalizing the above measure(s) for addition to the *Internal Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	443	N/A	MIPS CQM	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 32994), we are finalizing the above measure(s) for removal from the *Internal Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQM	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQM	Process	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance	We proposed including this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that this measure is highly relevant to this specialty as they often play a critical role in treating fractures, including vertebral compression fractures associated with osteoporosis. Effective communication with the physician managing ongoing care ensures a seamless transition from procedural intervention to long-term management, optimizing recovery and preventing complications.[583] Additionally, osteoporosis management is directly connected to many fracture conditions treated by interventional radiologists; ensuring appropriate post-fracture care, including evaluation and treatment for osteoporosis, helps reduce the risk of recurrent fractures.[584] This specialty has become increasingly involved in management of fractures that result from benign conditions like osteoporosis by using interventional techniques, such as image-guided osteoplasty and screw-mediated osteosyntheses.[585] Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[583] Cazzato, R. L., Dalili, D., De Marini, P., Koch, G., Autrusseau, P. A., Weiss, J., Auloge, P., Garnon, J., & Gangi, A. (2023). Bone Consolidation: A Practical Guide for the Interventional Radiologist. Cardiovascular and Interventional Radiology, 46(11), 1458–1468. https://doi.org/10.1007/s00270-022-03340-7.

[584] See footnote Cazzato et al., 2023.

[585] See footnote Cazzato et al., 2023.

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services	We proposed including this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that this quality measure is highly relevant to IR because accurate medication documentation is critical for ensuring patient safety during minimally invasive procedures. Many IR procedures, such as angiography, biopsies, or embolization, require careful consideration of a patient's current medications to assess risks like bleeding or contrast allergies.[586] This specialty also often admits patients and needs to ensure they receive their home medications while admitted. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[586] Alghamdi, D. S., Alhrasen, M., Kassem, A., Alwagdani, A., Tourkmani, A. M., Alnowaiser, N., Al Barakah, Y., & Alotaibi, Y. K. (2023). Implementation of Medication Reconciliation at Admission and Discharge in Ministry of Defense Health Services Hospitals: A Multicentre Study. BMJ Open Quality, 12(2), e002121. https://doi.org/10.1136/bmjoq-2022-002121.

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons	We proposed including this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that this quality measure is highly relevant to IR as it reflects important facets of procedural success and patient safety. This measure directly addresses procedure-specific outcomes, particularly for complex interventions such as embolization or vascular access. Adding this measure to this specialty set can support positive outcomes for IR procedures. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons	We proposed including this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that interventional radiologists commonly complete surgical procedures where appropriate management through supportive care can help decrease avoidable 30-day reoperation due to surgical complications. This measure reflects important facets of procedural success and patient safety directly addressing procedure-specific outcomes, particularly for complex interventions such as embolization or vascular access. This measure will help encourage appropriate management and avoidance of unnecessary and costly procedures. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons	We proposed including this measure in the Interventional Radiology (IR) specialty set as the measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that this quality measure is important for this specialty as it impacts patient safety and procedural success. This quality measure ensures proper precautions are taken to minimize infection risk, such as utilizing proper skin preparations, sterile techniques, and pre-procedural antibiotics, considering the importance of these interventions. To help keep complications to a minimum, it's crucial for all radiologists to understand and adhere to sterile techniques for better patient care. By following strict aseptic and sterile techniques, radiologists can minimize IR procedure complications.[587] Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[587] Mukund, A., Bhardwaj, K., & Mohan, C. (2019). Basic Interventional Procedures: Practice Essentials. The Indian Journal of Radiology & Imaging, 29(2), 182–189. https://doi.org/10.4103/ijri.IJRI_96_19.

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons	We proposed including this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that this quality measure is key to this specialty to ensure proper risk assessments and communication are prioritized prior to IR procedures. Patients undergoing IR procedures should receive a thorough preoperative evaluation. The addition of this measure to this specialty set helps ensure clinicians adhere to these practices to guide them to implement the most appropriate management plan, avoid unnecessary procedures, and prevent complications to achieve a successful outcome.[588] This will help ensure personalized risks of postoperative complications are appropriately assessed prior to procedures using a clinical data-based, patient-specific risk calculator and discussed with the patient. Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[588] Taslakian, B., Georges Sebaaly, M., & Al-Kutoubi, A. (2016). Patient Evaluation and Preparation in Vascular and Interventional Radiology: What Every Interventional Radiologist Should Know (Part 1: Patient Assessment and Laboratory Tests). Cardiovascular and Interventional Radiology, 39(3), 325–333. https://doi.org/10.1007/s00270-015-1228-7.

B.20. Interventional Radiology

MEASURES FINALIZED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance	We proposed including this measure in the Interventional Radiology (IR) specialty set as this measure is clinically relevant to this specialty type. We agreed with interested parties' feedback that this measure is highly relevant to this specialty as they often play a critical role in treating fractures, including vertebral compression fractures associated with osteoporosis. Effective communication with the physician managing ongoing care ensures a seamless transition from procedural intervention to long-term management, optimizing recovery and preventing complications.[589] Additionally, osteoporosis management is directly connected to many fracture conditions treated by interventional radiologists; ensuring appropriate post-fracture care, including evaluation and treatment for osteoporosis, helps reduce the risk of recurrent fractures.[590] This specialty has become increasingly involved in management of fractures that result from benign conditions like osteoporosis by using interventional techniques, such as image-guided osteoplasty and screw-mediated osteosyntheses.[591] Enhancing the IR-related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[589] See footnote Cazzato et al., 2023.
[590] See footnote Cazzato et al., 2023.
[591] See footnote Cazzato et al., 2023.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (90 FR 32996 through 33002), we are finalizing the above measure(s) for addition to the *Interventional Radiology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INTERVENTIONAL RADIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33003), we are finalizing the above measure(s) for removal from the *Interventional Radiology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v14	eCQM	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS137v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
§	N/A / N/A	366	CMS136v15	eCQM	Process	**Follow-Up Care for Children Prescribed ADHD Medication:** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	382	CMS177v14	eCQM	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§ ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33009), we are finalizing the above measure(s) for removal from the *Mental/Behavioral Health and Psychiatry Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS12 2v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	400	N/A	MIPS CQM	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years who have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQM	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis (HD) patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	1662/ N/A	489	N/A	MIPS CQM	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within the 12-month measurement period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	510	N/A	MIPS CQM	Process	**First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR):** The number of newly initiated patients on dialysis in a practitioner group who are under the age of 75 and were either listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis	Centers for Medicare & Medicaid Services
	N/A / N/A	511	N/A	MIPS CQM	Process	**Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW):** The measure tracks dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). This measure is a risk-adjusted percentage of waitlist events among dialysis patients.	Centers for Medicare & Medicaid Services

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	512	N/A	MIPS CQM	Process	**Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR):** The number of prevalent dialysis patients in a practitioner group who are	Centers for Medicare & Medicaid Services	We proposed including this measure in the Nephrology specialty set as this measure is clinically relevant to this clinician type. The maintenance of end stage renal disease patients in active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.		transplantation.[592] This measure focuses specifically on the outcome of waitlisting for patients on dialysis and is appropriate to this specialty as nephrologists are at the forefront of caring for this patient population. Nephrologists exert substantial control over processes that result in waitlisting and optimizing the health of patients to ensure early access to the waitlist, which has been demonstrated to be particularly beneficial.[593] These processes include proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, and assisting patients with completion of the transplant evaluation process.[594] These activities address the specific healthcare needs of patients on dialysis and are directed by dialysis practitioners aiming to achieve suitability for kidney transplantation.[595] Enhancing the nephrology related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of appropriate treatment for patients on dialysis. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (90 FR 33013 through 33014), we are finalizing the above measure(s) for addition to the *Nephrology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

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[592] See footnote Meier-Kriesche et al., 2002.
[593] See footnote Meier-Kriesche et al., 2002.
[594] See footnote Ashby et al., 2007.
[595] See footnote Satayathum et al., 2005.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEPHROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33015), we are finalizing the above measure(s) for removal from the *Nephrology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQM	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
	N/A / N/A	291	N/A	MIPS CQM	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQM	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression).	American Academy of Neurology
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.23. Neurology

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed including this measure in the Neurology specialty set as we agreed with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[596] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure will help fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[597] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and will promote more universal adoption of best practices to support shared decision making.[598] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family members or other caregivers.[599] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[596] See footnote Frosch et al., 2012.
[597] See footnote Teno et al., 2004.
[598] See footnote National Consensus Project for Quality Palliative Care, 2018.
[599] See footnote Meier, 2011.

B.23. Neurology

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	513	N/A	MIPS CQM	Process	**Patient Reported Falls and Plan of Care:** Percentage of patients (or caregivers as appropriate) with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who reported a fall occurred and those that fell had a plan of care for falls documented at every visit.	American Academy of Neurology	We proposed including this measure in the Neurology specialty set as this measure is clinically relevant to this clinician type. Neurologists are medical doctors who specialize in diagnosing and treating patients with neurologic disorders whose incidence of falls is reported as 2 to 4 times higher than in healthy subjects of similar age.[600] Several studies address the negative impact falls have on expediting neurologic morbidity and slowing progress toward recovery.[601] Falls can negatively impact quality of life. This stresses the importance of prioritizing falls assessment and promoting strategies that aim at preventing or reducing the incidence of falls in the neurologic patient population.[602] Enhancing the neurology related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and will elevate the importance of addressing a patient's increased falls risk when diagnosed with a neurologic condition.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported adding measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this specialty set. One of the commenters requested adding this measure to all specialty sets.

Response: We thank the commenters for supporting the addition of this measure to the Neurology specialty set. We encourage the commenter to request this measure be added to other specialty sets through the Solicitation for Specialty Sets process.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33019 through 33021), we are finalizing the above measure(s) for addition to the *Neurology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

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[600] See footnote Ehrhardt et al., 2020.

[601] Skolka, M. P., Neth, B. J., Brown, A., Steel, S. J., Hacker, K., Arnold, C., Toledano, M., & Mustafa, R. (2023). Improving Neurology Inpatient Fall Rate: Effect of a Collaborative Interdisciplinary Quality Improvement Initiative. Mayo Clinic Proceedings. Innovations, Quality & Outcomes, 7(4), 267–275. https://doi.org/10.1016/j.mayocpiqo.2023.05.004.

[602] Hunderfund, A. N., Sweeney, C. M., Mandrekar, J. N., Johnson, L. M., & Britton, J. W. (2011). Effect of a Multidisciplinary Fall Risk Assessment on Falls Among Neurology Inpatients. Mayo Clinic Proceedings, 86(1), 19–24. https://doi.org/10.4065/mcp.2010.0441.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	290	N/A	MIPS CQM	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	419	N/A	MIPS CQM	Process	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our responses.

Comment: A commenter opposed removal of measures Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease and Q419: Overuse of Imaging for the Evaluation of Primary Headache from this specialty set, indicating removal of these measures would leave a gap in measures for neurology.

The commenter also opposed removal of measures Q487: Screening for Social Drivers of Health and Q498: Connection to Community Service Provider from all proposed specialty sets. See Table C.8 of this Appendix for further information.

Response: We acknowledge the concerns expressed by the commenter. As mentioned in Tables C.3 and C.5 of this Appendix, measures Q290 and Q419 are extremely topped out which demonstrates they have become a standard of care. By removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement and focus specialty sets on areas with greater room for improvement to drive more meaningful gains in quality of care. We acknowledge that removal of these measures decreases the number of available measures for this specialty; however, there are policies in place, such as Eligible Measure Applicability (EMA) and denominator reduction to account for this when working to meet MIPS quality performance category requirements. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2025 Benchmark File. We

encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

As discussed under Tables C.8 and C.9 of this Appendix, measures Q487 and Q498 are process measures that no longer address a priority area and will no longer be considered high-priority measures. As explained in the removal rationale, removing these measures aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33022), we are finalizing the above measure(s) for removal from the *Neurology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy**: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	344	N/A	MIPS CQM	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
! (Outcome)	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROSURGICAL SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33025), we are finalizing the above measure(s) for removal from the *Neurosurgical Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS122v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	NA / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS155v14	eCQM	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. ● Percentage of patients with height, weight, and body mass index (BMI) percentile documentation ● Percentage of patients with counseling for nutrition ● Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR ADDITION TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	We proposed including this measure in the Nutrition/ Dietician specialty set as this measure is clinically relevant to this clinician type. We agreed with interested parties' feedback that Registered Dietician Nutritionists (RDNs) are uniquely qualified to offer essential education and support to caregivers regarding feeding assistance, managing behavioral challenges related to food, and addressing palliative food and fluid needs especially with patients diagnosed with dementia.[603] RDNs can also help caregivers to recognize declines in a patient's physical capacity and advise them on identifying malnutrition risks, developing tailored interventions that support both the patient and caregiver, and assist in planning appropriate adjustments to nutritional care plans and feeding techniques as the disease progresses.[604] This specialty is integral to the process of enhancing the quality of life and nutritional status of older adults through individualized nutrition approaches.[605] Malnutrition is a critical concern in dementia care and can exacerbate symptoms and increase mortality rates.[606] These efforts align with best practices in dementia care, ensuring comprehensive and compassionate management.[607] Given RDNs' role in educating and supporting caregivers in dementia care, their involvement ensures a holistic approach to care by addressing both the nutritional and behavioral needs of patients, ultimately improving the quality of life for individuals with dementia.[608] Enhancing

[603] Sanders, C. L., Wengreen, H. J., Schwartz, S., Behrens, S. J., Corcoran, C., Lyketsos, C. G., Tschanz, J. T., & Cache County Investigators (2018). Nutritional Status is Associated With Severe Dementia and Mortality: The Cache County Dementia Progression Study. Alzheimer Disease and Associated Disorders, 32(4), 298–304. https://doi.org/10.1097/WAD.0000000000000274.

[604] See footnote Sanders et al., 2018.

[605] Dorner, B., & Friedrich, E. K. (2018). Position of the Academy of Nutrition and Dietetics: Individualized Nutrition Approaches for Older Adults: Long-Term Care, Post-Acute Care, and Other Settings. Journal of the Academy of Nutrition and Dietetics, 118(4), 724–735. https://doi.org/10.1016/j.jand.2018.01.022.

[606] See footnote Sanders et al., 2018.

[607] Molony, S. L., Kolanowski, A., Van Haitsma, K., & Rooney, K. E. (2018). Person-Centered Assessment and Care Planning. The Gerontologist, 58(suppl_1), S32–S47. *https://doi.org/10.1093/geront/gnx173*.

[608] Yerstein, O., & Mendez, M. F. (2020). Dietary Recommendations for Patients with Dementia. Alzheimer's & Dementia (New York, N. Y.), 6(1), e12011. https://doi.org/10.1002/trc2.12011.

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								the nutrition/dietician related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this specialty set will elevate the importance of assessing and addressing nutrition challenges experienced by patients with dementia. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported adding measure Q288: Dementia: Education and Support of Caregivers for Patients with Dementia to this specialty set.

Response: We thank the commenters for supporting the addition of this measure to the Nutrition/Dietician specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33028 through 33029), we are finalizing the above measure(s) for addition to the *Nutrition/Dietician Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NUTRITION/DIETICIAN SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33030), we are finalizing the above measure(s) for removal from the *Nutrition/Dietician Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS165v 14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124v 14	eCQM	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v 14	eCQM	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQM	Outcome	**Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQM	Process	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Safety)	N/A / N/A	504	N/A	MIPS CQM	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	443	N/A	MIPS CQM	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set.

Comment: A commenter recommended that if measure Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females is removed from this specialty that it be replaced with a similar cervical screening measure such as NCQA's Cervical Cancer Screening measure.

The commenter also requested that measures Q487: Screening for Social Drivers of Health, Q498: Connection to Community Service Provider, and Q508: Adult COVID-19 Vaccination Status not be removed from this specialty set.

Response: We thank the commenter for their comment and note that NCQA's Cervical Cancer Screening measure is already in MIPS and previously finalized within this specialty set with an eCQM collection type and measure ID: Q309/CMS124v14.

As discussed under Tables C.8, C.9, and C.10 of this Appendix, measures Q487, Q498, and Q508 are process measures that no longer address a priority area and will no longer be considered high-priority measures. As explained in the removal rationale, removing these measures aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33037), we are finalizing the above measure(s) for removal from the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v15	eCQM, MIPS CQM	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v14	eCQM, MIPS CQM	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient experience)	0383 / N/A	144	N/A	MIPS CQM	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE).	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQM	Process	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	1859 / N/A	451	N/A	MIPS CQM	Process	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor (EGFR) monoclonal antibody (MoAb) therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed before initiation of anti-EGFR MoAb.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQM	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0216 / N/A	457	N/A	MIPS CQM	Process	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v9	eCQM	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
	N/A / N/A	490	N/A	MIPS CQM	Process	**Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
! (Appropriate Use)	N/A / N/A	506	N/A	MIPS CQM	Process	**Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy:** Percentage of patients, aged 18 years and older, with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.	Society for Immunotherapy of Cancer (SITC)
	N/A / N/A	507	N/A	MIPS CQM	Process	**Appropriate Germline Testing for Ovarian Cancer Patients:** Percentage of patients, aged 18 and older, diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33043), we are finalizing the above measure(s) for removal from the *Oncology/Hematology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS 129v15	eCQM, MIPS CQM	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS 157v14	eCQM, MIPS CQM	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQM	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / 0086e	012	CMS143v14	eCQM	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits during the measurement period.	American Academy of Ophthalmology
! (Care Coordination)	N/A / N/A	019	CMS142v14	eCQM	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure, MIPS CQM	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS13 3v14	eCQM, MIPS CQM	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQM	Patient Engagement/ Experience	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQM	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQM	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
* ! (Outcome)	N/A / N/A	389	N/A	MIPS CQM	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	499	N/A	MIPS CQM	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists
*	N/A / N/A	500	N/A	MIPS CQM	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.	American Society of Retina Specialists
*	N/A / N/A	501	N/A	MIPS CQM	Process	**Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.	American Society of Retina Specialists

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE OPHTHALMOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33051), we are finalizing the above measure(s) for removal from the *Ophthalmology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.29. Optometry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.29. Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	019	CMS142v14	eCQM	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v14	eCQM, MIPS CQM	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	178	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQM	Process	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQM	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v14	eCQM	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	470	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR. tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE ORTHOPEDIC SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33063), we are finalizing the above measure(s) for removal from the *Orthopedic Surgery Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.31. Otolaryngology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33068), we are finalizing the above measure(s) for removal from the *Otolaryngology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.32. Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no proposed changes.

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQM	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status:**	College of American Pathologists

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.	

B.33. Pediatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date**.**	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / 3755e	205	CMS1188v3	eCQM, MIPS CQM	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS155v14	eCQM	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS117v14	eCQM	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS137v14	eCQM	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v14	eCQM	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	366	CMS136v15	eCQM	Process	**Follow-Up Care for Children Prescribed ADHD Medication:** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159v14	eCQM, MIPS CQM	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	382	CMS177v14	eCQM	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* §	N/A / N/A	394	N/A	MIPS CQM	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PEDIATRICS SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33075), we are finalizing the above measure(s) for removal from the *Pediatrics Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.34. Physical Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PHYSICAL MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33078), we are finalizing the above measure(s) for removal from the *Physical Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.35. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v14	eCQM	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.	American Academy of Neurology

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
	N/A / N/A	291	N/A	MIPS CQM	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Patient Safety)	0101 / N/A	318	CMS139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.35. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	We proposed including this measure in the Physical Therapy/Occupational Therapy specialty set as we agreed with interested parties' feedback that adding this measure to this specialty set will help to broaden the patient population being screened for high blood pressure. Hypertension (HTN) is among the leading global preventable risk factors for cardiovascular disease and premature mortality.[609] Early detection and effective management of HTN have demonstrated significant reductions in mortality, morbidity rate, and health care costs. improves detection rates and medical management.[610] The physical therapist/ occupational therapist specialists may serve as the first point of contact into the health care system, thereby necessitating a need for routine blood pressure (BP) monitoring.[611] Leading physical therapy professional organizations include statements in their guidelines that suggest that physical therapists have a duty to provide a standard of care that protects the safety and optimizes the overall health of patients under their care.[612] Interdisciplinary care is vital, and it should be the responsibility of all clinician types to address health promotion and wellness, and prevention, delay, or management of acute or chronic diseases and conditions. Enhancing the physical therapy/occupational therapy related measure inventory could help to ensure broad specialty coverage by having measures available that are robust and clinically relevant to clinicians within this specialization. This measure complements other measures within their set and adding this measure to this

[609] Severin, R., Sabbahi, A., Albarrati, A., Phillips, S. A., & Arena, S. (2020). Blood Pressure Screening by Outpatient Physical Therapists: A Call to Action and Clinical Recommendations. Physical Therapy, 100(6), 1008–1019. https://doi.org/10.1093/ptj/pzaa034.
[610] See footnote Severin et al., 2020.
[611] See footnote Severin et al., 2020.
[612] See footnote Severin et al., 2020.

B.35. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								specialty set will elevate the importance of early detection of HTN across specialists. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the addition of measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented to this specialty set. One of the commenters indicated that inclusion of this measure emphasizes the important role physical therapists play in identifying complexities and comorbidities and establishing a treatment plan that includes appropriate referrals, as well as prescribing interventions that will effectively and safely address the patient in the context of their medical status.

Response: We thank the commenters for supporting the addition of this measure to the Physical Therapy/Occupational Therapy specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33085 through 33086), we are finalizing the above measure(s) for addition to the *Physical Therapy/Occupational Therapy Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/ OCCUPATIONAL THERAPY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33086), we are finalizing the above measure(s) for removal from the *Physical Therapy/Occupational Therapy Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.36. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PLASTIC SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33089), we are finalizing the above measure(s) for removal from the *Plastic Surgery Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.37. Podiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS 139v14	eCQM	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PODIATRY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33092), we are finalizing the above measure(s) for removal from the *Podiatry Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.38. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059 / N/A	001	CMS 122v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%**: Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS 347v9	eCQM, MIPS CQM	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	475	CMS 349v8	eCQM	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
*	N/A / N/A	488	CMS 951v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance
	N/A / N/A	497	N/A	MIPS CQM	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33098), we are finalizing the above measure(s) for removal from the *Preventive Medicine Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQM	Process	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic and were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	236	CMS165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.39. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed including this measure in the Pulmonology specialty set as we agreed with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and facility settings.[613] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure will help fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[614] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care.

[613] See footnote Frosch et al., 2012.
[614] See footnote Teno et al., 2004.

B.39. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and will promote more universal adoption of best practices to support shared decision making.[615] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family members or other caregivers.[616] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported adding measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this specialty set. One of the commenters recommended this measure be added to all specialty sets.

Response: We thank the commenters for supporting the addition of this measure to the Pulmonology specialty set. We encourage the commenter to request this measure be added to other specialty sets through the Solicitation for Specialty Sets process.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33101 through 33102), we are finalizing the above measure(s) for addition to the *Pulmonology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[615] See footnote National Consensus Project for Quality Palliative Care, 2018.
[616] See footnote Meier, 2011.

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PULMONOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33103), we are finalizing the above measure(s) for removal from the *Pulmonology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.40. Rheumatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the performance period.	American College of Rheumatology
	N/A / N/A	178	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQM	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	236	CMS165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee Quality Assurance

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE RHEUMATOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33108), we are finalizing the above measure(s) for removal from the *Rheumatology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.41. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0067 / N/A	006	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS145v14	eCQM, MIPS CQM	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS144v14	eCQM, MIPS CQM	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022 / N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
*	3620 / N/A	493	N/A	MIPS CQM	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B.	National Committee for Quality Assurance

B.41. Skilled Nursing Facility

MEASURES FINALIZED FOR ADDITION TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed including this measure in the Skilled Nursing Facility specialty set as we agreed with interested parties' feedback that this measure is clinically relevant to this clinician type. Palliative care has expanded rapidly in recent years across inpatient, ambulatory, home-based, and

MEASURES FINALIZED FOR ADDITION TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.		facility settings.[617] Inclusion of this measure can help ensure that more specialist types are equipped to better manage seriously ill patients' access to high-quality palliative care. This patient-reported outcome measure will help fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models[618] and is specified to allow non-palliative care specialists who treat patients with serious illness to report the measure and encourages more comprehensive care. Increasing the clinician's focus on managing the experiences of patients, families, and caregivers is critical to advancing person-centered care and will promote more universal adoption of best practices to support shared decision making.[619] Studies have shown that adding palliative care to the plan of care for patients with serious illness results in better symptom management and communication with health care providers, as well as decreased strain on family members or other caregivers.[620] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2026 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

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[617] See footnote Frosch et al., 2012.
[618] See footnote Teno et al., 2004.
[619] See footnote National Consensus Project for Quality Palliative Care, 2018.
[620] See footnote Meier, 2011.

Comment: A few commenters supported adding measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this specialty set. One of the commenters recommended adding this measure to all specialty sets.

Response: We thank the commenters for supporting the addition of this measure to the Skilled Nursing Facility specialty set. We encourage the commenters to request this measure be added to other specialty sets through the Solicitation for Specialty Sets process.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33111 through 33112), we are finalizing the above measure(s) for addition to the *Skilled Nursing Facility Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE SKILLED NURSING FACILITY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33112), we are finalizing the above measure(s) for removal from the *Skilled Nursing Facility Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.42. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQM	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
	N/A / N/A	286	N/A	MIPS CQM	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	288	N/A	MIPS CQM	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Academy of Neurology / American Psychiatric Association
	N/A / N/A	291	N/A	MIPS CQM	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression).	American Academy of Neurology

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33115), we are finalizing the above measure(s) for removal from the *Speech Language Pathology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.43. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQM	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQM	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQM	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization.	Society of Thoracic Surgeons

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQM	Outcome	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE THORACIC SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33118), we are finalizing the above measure(s) for removal from the *Thoracic Surgery Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.44. Urgent Care

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v14	eCQM, MIPS CQM	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v14	eCQM, MIPS CQM	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	317	CMS22 v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
*	N/A / N/A	488	N/A	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE URGENT CARE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33121), we are finalizing the above measure(s) for removal from the *Urgent Care Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.45. Urology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v15	eCQM, MIPS CQM	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0022/ N/A	238	CMS156v14	eCQM, MIPS CQM	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	317	CMS22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQM	Outcome	**Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogyneco-logic Society
* § ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQM	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0216/ N/A	457	N/A	MIPS CQM	Process	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v9	eCQM	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771v7	eCQM	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Appropriate Use)	N/A/ N/A	481	CMS646v6	eCQM	Process	**Intravesical Bacillus-Calmette -Guerin for Non-Muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
*	N/A / N/A	488	CMS951v4	eCQM, MIPS CQM	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13–item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.45. Urology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	508	N/A	MIPS CQM	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33127), we are finalizing the above measure(s) for removal from the *Urology Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.46. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v15	eCQM, MIPS CQM	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS 138v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	236	CMS 165v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	259	N/A	MIPS CQM	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgery
	N/A / N/A	317	CMS 22v14	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQM	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
* ! (Outcome)	N/A / N/A	357	N/A	MIPS CQM	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v14	eCQM, MIPS CQM	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • High Intensity Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE VASCULAR SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	487	N/A	MIPS CQM	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	498	N/A	MIPS CQM	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN	This measure was proposed for removal beginning with the CY 2026 performance period/2028 MIPS payment year. See Table Group C of this Appendix for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (90 FR 33131), we are finalizing the above measure(s) for removal from the *Vascular Surgery Specialty Set* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

Table Group C: Previously Finalized Quality Measures Finalized for Removal for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

In this final rule, we are removing 10 previously finalized MIPS quality measures for the CY 2026 performance period/2028 MIPS payment year and future years. These measures are discussed in detail in the removal tables below.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discuss our incremental approach to removing process measures. Further considerations are given in the evaluation of the measure's performance data to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion we use for the removal of measures includes extremely topped-out measures, which refers to measures topped out with an average (mean) performance rate between 98-100 percent. For a measure proposed for removal due to criteria relating to the benchmark and performance data, further information regarding 2025 MIPS benchmarking data can be located at https://qpp.cms.gov/benchmarks.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discusses our incremental approach to removing process measures. The criteria used to determine the removal of a quality measure were codified at 414.1330(c) in the CY 2025 PFS final rule (89 FR 98561).

We requested comments on these measure removals.

C.1. Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	185
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286). This measure's continued topped-out status is based on the current 2025 MIPS benchmarking data located at https://qpp.cms.gov/benchmarks, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter opposed the removal of measure Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use and urged CMS to use its discretion and maintain the measure in MIPS. The commenter stated this measure is vital to ensuring evidence-based care, reducing unnecessary costs, and supporting preventive health priorities.

The commenter cited the following about measure Q185:

- Adheres to Evidence-Based Guidelines for Colonoscopy Surveillance: Ensures patients with adenomatous polyps receive colonoscopies at appropriate 3 to 5-year intervals based on risk, preventing unnecessary procedures, complications, anxiety, and added costs.
- Reduces Unnecessary Healthcare Costs and Improves Cost-Effectiveness: Prevents overuse of colonoscopies, lowering direct and indirect costs while preserving patient safety and advancing value-based care.
- Promotes Upstream Drivers of Health and Population Adjustment: Supports equitable, guideline-based care, reducing inappropriate screenings in vulnerable and underserved populations and addressing disparities in access and adherence.
- Aligns with CMS' Long-Term Goals for Quality Measurement: Advances preventive, patient-centered care and efficiency; removing this measure would undermine efforts to reduce waste, improve outcomes, and support high-value care.

Another commenter requested that Q185 be retained as it will help ensure continued clinician adherence to evidence-based intervals and prevent unnecessary procedures.

Response: We thank the commenters for their feedback. While we agree the concept is important to quality care, the removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is assessed for the quality action or not, it should still be completed as a matter of high-quality care. The data shows the measure has reached the end of its topped-out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement and focus specialty sets on areas with greater room for improvement to drive more meaningful gains in quality of care. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2025 Benchmark File.

We encourage the commenters to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33132), we are finalizing the removal of measure Q185 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.2. Sentinel Lymph Node Biopsy for Invasive Breast Cancer

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	264
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.
Measure Steward:	American Society of Breast Surgeons
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) at the measure steward's request because it is not aligned with current clinical guidelines and will no longer be maintained for inclusion.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported CMS' proposal to remove measure Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer from MIPS. The commenter explained, as the measure steward, they decided to retire the measure due to declining use and lack of a benchmark since 2021. These trends reflect evolving clinical practice and new evidence showing sentinel lymph node biopsy is not recommended for many patients with early-stage invasive breast cancer, reducing the measure's applicability.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: A commenter expressed concern that many topped-out measures are oncology- and cancer-specific and removing them without replacement would leave hospitals with limited meaningful reporting options. They warned this would reduce the relevance of the Advancing Cancer Care MVP and weaken alignment between QPP requirements and oncology practice. The commenter urged CMS to ensure that any oncology measures slated for retirement are replaced with suitable alternatives that reflect current standards of care and meaningful outcomes for cancer patients.

Response: We thank the commenter for their comment. We recognize the importance of the clinical area the measure focuses on and do not want to limit measures applicable to oncology within MIPS. However, as noted in the rationale for removal, the measure will no longer be maintained by the measure steward because it is not aligned with current clinical guidelines. We also note the Advancing Cancer Care MVP still contains a good number of meaningful quality and QCDR measures to ensure applicability and clinician choice for selection. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33132), we are finalizing the removal of measure Q264 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.3. Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	290
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.31 percent and as such is considered extremely topped out. The average performance rate is based on the current 2025 MIPS benchmarking data located at https://qpp.cms.gov/benchmarks. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received no public comments on the proposed removal of this measure. For the reasons stated above and in the proposed rule (90 FR 33133), we are finalizing the removal of measure Q290 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.4. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	322
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this inverse measure, 0.03 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). For an inverse measure, a lower calculated performance rate indicates better clinical care or control. The average performance rate is based on the current 2025 MIPS benchmarking data located at https://qpp.cms.gov/benchmarks. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support removal of measure Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients but acknowledged CMS' rationale for proposing removal of measure Q322 due to topped-out performance. The commenter cautioned against eliminating one of the few cardiology-specific efficiency measures without a replacement. Full comment is under B.4a Removal Table of this Appendix.

Response: We thank the commenter for their feedback and acknowledge that removal of this measure decreases the number of available measures for certain specialists; however, there are policies in place, such as Eligible Measure Applicability (EMA) and denominator reduction to account for this when working to meet MIPS quality performance category requirements. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement and focus specialty sets on measures with greater room for improvement to drive more meaningful gains in quality. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2025 Benchmark File.

We encourage the commenters to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33133), we are finalizing the removal of measure Q322 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.5. Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	419
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this inverse measure, 0.55 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). For an inverse measure, a lower calculated performance rate indicates better clinical care or control. The average performance rate is based on the current 2025 MIPS benchmarking data located at https://qpp.cms.gov/benchmarks. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter did not support removing measure Q419: Overuse of Imaging for the Evaluation of Primary Headache despite its extremely topped-out status. They explained that for many specialists, such as interventional pain management clinicians who lack quality measures aligned with their specialty, this measure is integral to their quality category contribution. Even though it is topped out, the 7 points it provides is higher than many other measures they report on, and its removal without a comparable replacement would disadvantage clinicians' quality scores. Other commenters also opposed removal of measure Q419, with a commenter stating that this may lead to an overuse of CT and MRI services, which in addition to increasing patient exposure to unnecessary radiation, would also result in higher health system costs.

Response: While we agree that the intent of measure Q419 is to discourage unnecessary use of CT and MRI imaging for evaluation of primary headaches, this measure is extremely topped out, which demonstrates it has become a standard of care not to use CT and MRI imaging for evaluation of primary headaches when clinical indications are not present. We acknowledge that removal of this measure decreases the number of available measures for certain specialists; however, there are policies in place, such as Eligible Measure Applicability (EMA) and denominator reduction to account for this when working to meet MIPS quality performance category requirements. Additionally, these nuances, measure availability, including specialty specific, and scoring, are considered when reviewing the MIPS quality measure inventory. Lastly, we encourage the commenter to reach out to measure developers/stewards to develop new outcome/high priority measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33134), we are finalizing the removal of measure Q419 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.6. Perioperative Temperature Management

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	424
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.
Measure Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance on this measure, 98.55 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance rate is based on the current 2025 MIPS benchmarking data located at https://qpp.cms.gov/benchmarks. For more information on benchmarks, see the MIPS 2025 Quality Benchmarks User Guide at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3162/2025-Quality-Benchmarks-User-Guide.pdf.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed removing measure Q424: Perioperative Temperature Management, emphasizing that it is anesthesiology's only outcome measure in MIPS and represents a critical workflow for preserving patient safety and preventing adverse events, such as perioperative hypothermia and postoperative infections. They noted that most anesthesia-specific measures are already topped out and removing measure Q424 would make it harder for clinicians to meet reporting requirements, forcing them to rely on less relevant measures. The commenters explained that while QCDRs are working to develop new anesthesia measures, broadly applicable options remain limited, and eliminating measure Q424 could increase patient harm and create unnecessary burden for anesthesiologists. Another commenter requested the measure be retained for 1 more year to allow time to transition the Normothermia Outcome (ASC-13) measure, used in the Ambulatory Surgical Center Quality Reporting program, into MIPS for 2027. The commenter explained that while ASC-13 is currently submitted via a web-based tool, CMS could enable collection through registries and other electronic resources, and retaining measure Q424 in 2026 would provide time to coordinate with ASCQR staff to adapt the normothermia measure for MIPS reporting.

Response: We thank the commenters for their feedback. While we agree the intent of measure Q424 addresses a critical element in promoting strategies to prevent perioperative hypothermia, removal of the measure does not preclude the quality action from continuing. This measure shows continued high performance, demonstrating these strategies have become a standard of care. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement and focus specialty sets on areas with greater room for improvement to drive more meaningful gains in quality care. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the 2025 Benchmark File.

We also acknowledge the removal of this measure decreases the number of available measures for certain specialists; however, there are policies in place, such as Eligible Measure Applicability (EMA) and denominator reduction to account for this when working to meet MIPS quality performance category requirements. Additionally, these nuances, measure availability, including specialty specific, and scoring, are considered when reviewing the MIPS quality measure inventory.

We encourage the commenters to reach out to the measure developers/stewards to ensure the measure meets MIPS requirements and submit it to the Call for Measures for possible future implementation. We appreciate the suggestion to adapt ASC-13 for MIPS and will consider it for future performance years. We appreciate the potential for alignment across programs if developed for clinicians and deemed appropriate for MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33134), we are finalizing the removal of measure Q424 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.7. Non-Recommended Cervical Cancer Screening in Adolescent Females

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	443
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the measure steward will no longer maintain the measure.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed removal of measure Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: A commenter recommended that if measure Q443 is removed from MIPS that it be replaced with a similar cervical screening measure such as NCQA's digital Cervical Cancer Screening measure.

Response: We thank the commenter for their comment and note that NCQA's Cervical Cancer Screening measure is already in MIPS with an eCQM collection type and measure ID: Q309/CMS124v14.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33135), we are finalizing the removal of measure Q443 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.8. Screening for Social Drivers of Health

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	487
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 87 FR 70253 through 70259) because it is a process measure that no longer addresses a priority area and will no longer be considered a high-priority measure. In the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765) rule, we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. Additionally, we sought to align with other quality programs. As indicated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule, the Screening for Social Drivers of Health (SDoH) measure was finalized for removal beginning with the CY 2024 reporting period/FY 2026 payment determination from the Hospital Inpatient Quality Reporting (IQR) (90 FR 37014) and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Programs (90 FR 37029). Further alignment is also finalized for the Inpatient Rehabilitation Facility (IRF) and Long-Term Care Hospital (LTCH) settings through finalized removal of SDoH related elements from standardized patient assessment reporting (90 FR 37037). Therefore, removing this measure aligned with the CMS Quality Measure Development Plan[621] through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses. We note that commenters mostly repeated the same points here for measure Q498: Connection to Community Service Provider, which is proposed for removal under Table C.9 of this Appendix.

Comment: A commenter noted they are committed to the importance of identifying and addressing health-related social needs (HRSNs) or upstream drivers of health; however, they supported the proposed removal of measure Q487: Screening for Social Drivers of Health due to concerns regarding lack of health information technology capabilities and interoperability, administrative burden, and lack of community resources. Another commenter supported the intent of the two health equity measures finalized for use in MIPS and MSSP but agreed with CMS' proposal to remove them. They explained that since the measures were finalized, concerns have been raised about the lack of supporting evidence and uncertainty about whether they would improve patient care. The commenter stated that CMS has not provided sufficient testing data on reliability and validity, with available information limited to two optional screening tools. The commenter also highlighted that clinicians may not be able to meet patient needs due to limited availability of resources, which varies by locality and type of service. The commenter noted that availability of services such as affordable housing and transportation depends on factors beyond clinician control.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

Comment: Many commenters opposed removing measure Q487. Key points included:

- Broad applicability and clinician flexibility: Measure Q487 is important for both primary and specialty clinicians, with commenters highlighting its particular value for clinicians who face very few reportable measures within traditional MIPS several MVPs. A commenter noted that removal of this measure would make it more difficult for entities to transition to MVP reporting.

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[621] CMS. (2016). CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/final-mdp.pdf.

- Support for vulnerable populations and chronic disease management: Commenters stressed its role in addressing social needs for older adults and patients with complex conditions, including screening for food insecurity, housing instability, and related risks. Commenters linked the measures to better management of diabetes, cardiovascular disease, obesity, and other chronic conditions, emphasizing the importance of addressing social and behavioral risk factors.
- Burden and workflow considerations: Collecting and using SDOH data is already common practice in healthcare, with electronic health records able to capture this information and the burden of collection minimal, with many practices having spent significant time and resources to construct workflows in order to collect SDOH information.
- Patient outcomes, system impact, and cost savings: Eliminating the measure could worsen outcomes, increase emergency department visits and readmissions, and reduce connections to community resources. Engaging community support resources for patients with unmet needs can improve mental health, increase access to care, and lower long-term healthcare costs. SDOH data also enable more accurate analyses of access, cost, and outcomes across populations.
- Complement to measure Q498 and alignment with CMS priorities: Several commenters noted that Q487 and Q498 together encourage consistent screening across five domains of social needs, helping clinicians identify where further assessment, services, or care modifications are needed to improve outcomes. Removing both measures would undermine efforts to improve health equity, risk stratification, and prevention of costly health declines. Commenters stated CMS has prioritized social needs and urged more attention to demographic factors affecting access to care.
- Clinician choice and alternatives: Commenters urged CMS to preserve measure Q487 as a reporting option to align with ongoing practice priorities and avoid forcing clinicians to use less relevant measures. A commenter suggested adding the Addressing Health Related Social Needs eCQM in place of measure Q487 as an alternative measure.

Overall, commenters urged CMS to retain measure Q487 or provide alternatives to maintain focus on social drivers of health as essential to patient well-being, disease prevention, and health equity. Commenters recommended refining the measure by combining questions for efficiency, supporting integration of SDOH screening into existing workflows, and ensuring data collection is paired with meaningful referrals to community and social services. They also suggested CMS consider broader strategies, such as new payment models, fee schedule reforms, additional improvement activities or quality measures, and facilitating interoperable data exchange.

Response: We thank the commenters for their feedback. This is a process measure that no longer addresses a priority area and will no longer be considered a high-priority measure. As explained, removing this measure aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers. While we agree that the concept is important to quality care for all, the removal of measure Q487 does not preclude the quality action from continuing. Whether the clinician/group is assessed for the quality action or not, it should still be completed as clinically appropriate as deemed by the clinician. Additionally, the removal of these measures is in accordance with already finalized proposals in other CMS programs, such as the Hospital IQR Program, maintaining alignment across programs as feasible. We note that specialty sets and MVPs were reviewed with sufficient measure choice in mind, and sufficient choice is maintained despite removal of this measure. We appreciate practices having workflows put in place to address health care for all. We also note that the Addressing Health Related Social Needs eCQM is not a MIPS measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33136), we are finalizing the removal of measure Q487 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.9. Connection to Community Service Provider

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	498
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Measure Steward:	OCHIN
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 88 FR 79574 through 79577) because it is a process measure that no longer addresses a priority area and will no longer be considered a high-priority measure. In the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765), we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. Additionally, we sought to align with other quality programs. As indicated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule, the Screen Positive Rate for Social Drivers of Health (SDoH) measure is finalized for removal beginning with the CY 2024 reporting period/FY 2026 payment determination from the Hospital Inpatient Quality Reporting (IQR) (90 FR 37014) and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Programs (90 FR 37029). Further alignment is also finalized for the Inpatient Rehabilitation Facility (IRF) and Long-Term Care Hospital (LTCH) settings through finalized removal of SDoH related elements from standardized patient assessment reporting (90 FR 37037). Therefore, removing this measure aligns with the CMS Quality Measure Development Plan[622] through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers, and reduce clinician burden of data collection as feasible.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported removing measure Q498: Connection to Community Service Provider due to limited health IT capabilities, interoperability challenges, administrative burden, and lack of community resources. Another commenter also supported removal, citing concerns raised since the measure was finalized about insufficient supporting evidence and uncertainty over whether it would improve patient care.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

Comment: Many commenters opposed removing measure Q498, with most repeating the same themes raised for measure Q487: Screening for Social Drivers of Health (see Table C.8 of this Appendix for more detail). In addition, commenters further emphasized that measure Q498 remains a high priority because connecting patients to resources such as nutrition and social support is essential to addressing social factors that affect health and aligns with CMS' prevention goals. They highlighted that measure Q498 complements measure Q487 by confirming whether patients who screen positive for barriers are connected to community service providers, ensuring follow-through and access to critical resources. Commenters cautioned that removing these measures would undermine progress in chronic disease management and weaken the infrastructure needed to support vulnerable populations. Given CMS' stated focus on prevention, chronic disease management, nutrition, and wellbeing, commenters urged CMS to retain this measure or provide alternatives that ensure evidence-based interventions and referral pathways are maintained.

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[622] See footnote CMS, 2016.

Response: We thank the commenters for their feedback. As noted above, this is a process measure that no longer addresses a priority area and will no longer be considered a high-priority measure. As explained, removing this measure aligns with the CMS Quality Measure Development Plan through maintaining a quality measure inventory that focuses on high-priority and outcome-based measures that align across programs and payers. While we agree that the concept is important to quality care for all, the removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is assessed for the quality action or not, it should still be completed as clinically appropriate as deemed by the clinician. Additionally, the removal of these measures is in accordance with already finalized proposals in other CMS programs, such as the Hospital IQR Program, maintaining alignment across programs as feasible.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33137), we are finalizing the removal of measure Q498 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

C.10. Adult COVID-19 Vaccination Status

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	508
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 89 FR 98608 through 98613) because it is a process measure, and we sought to align with other Medicare programs. In the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765) rule, we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. Additionally, we sought to align with other quality programs. As indicated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule, inpatient measure COVID–19 Vaccination Coverage Among Healthcare Personnel Measure was finalized for removal (90 FR 37012). This measure was also finalized for removal in the Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2026 and Updates to the IRF Quality Reporting Program final rule (90 FR 37702). We sought to align with these proposals to streamline clinical topics assessed across Medicare quality reporting programs.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2026 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed removal of measure Q508: Adult COVID-19 Vaccination Status due to concerns regarding lack of health information technology capabilities and interoperability, administrative burden, and lack of community resources. Another commenter supported removing measure Q508, citing unclear numerator specifications tied to changing CDC recommendations, which undermines reliability and validity. They noted difficulties tracking vaccinations given outside primary care and emphasized the measure lacked support from key review committees. They concluded it should not be included in MIPS until it undergoes sufficient testing with clear specifications and achieves consensus.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

Comment: Several commenters opposed removing measure Q508 because COVID-19 continues to burden adults, especially those with comorbidities or immunocompromised states, making vaccination measurement essential. Commenters cited the following:

- Retaining this measure ensures clinicians assess, recommend, and document vaccination—critical for preventing severe disease, reducing transmission, and protecting public health.
- Removal is premature given ongoing circulation, surges, and new variants; it risks lowering accountability and signaling vaccination is no longer a priority.
- Measure helps track disparities, protect vulnerable populations, and support rapid response to surges.
- Measure aligns with other adult immunization measures (influenza, pneumococcal), reinforcing vaccination as standard preventive care.
- COVID-19 hospitalizations, long COVID, and costs remain significant, justifying continued prioritization.
- Eliminating the measure would disrupt trend analyses and weaken long-term evaluation.
- Vaccination assessment is a low-cost, high-impact tool that strengthens the health system's response to respiratory disease.

- NCQA's 2026 HEDIS update introduced a COVID-19 indicator for adults ≥65[623] and commenters urged CMS to update measure Q493: Adult Immunization Status to align with NCQA's latest health plan level specifications to ensure continued vaccination focus for high-risk older adults if measure Q508 was removed.
- Emphasized vaccination's role in reducing morbidity and mortality for older adults and immunocompromised individuals, and noting recent FDA approval of updated vaccines, and recommended annual reevaluation and updates as new evidence emerges.

Response: As explained in the rationale above, outcome measures are more instrumental to improving the quality-of-care patients receive than process measures. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure. We also communicated to interested parties in the CY 2020 PFS final rule (84 FR 62957) and CY 2019 PFS final rule (83 FR 59763 through 59765) rule our desire to reduce the number of process measures within the MIPS quality measure set. The removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is assessed for the quality action or not, it should still be completed as clinically appropriate as deemed by the clinician. Additionally, the removal of these measures is in accordance with already finalized proposals in other CMS programs, such as the Hospital IQR Program, maintaining alignment across programs as feasible. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years for measure Q493.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33138), we are finalizing the removal of measure Q508 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[623] National Committee for Quality Assurance. (2025, August 1). HEDIS MY 2026: What's New, What's Changed, What's Retired. https://www.ncqa.org/blog/hedis-my-2026-whats-new-whats-changed-whats-retired/.

Table Group D: Finalized and Not Finalized Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

The D Tables within this final rule provide the substantive changes finalized and not finalized for the MIPS quality measures in CY 2026. Three measures have finalized substantive changes that will result in a new benchmark. All measures with substantive changes are discussed in detail in the tables below.

We note that some MIPS quality measures available in traditional MIPS and MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as finalized in the 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM)) is also specified as a collection type available for such measures described in Table Group D.

The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2026 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2026 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2027. The 2026 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types on the Quality Payment Program website at https://qpp.cms.gov. In addition, eCQMs that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2026 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has been added to all 2026 quality measure specifications in the form of a revised 'Instructions Note' to clearly identify if telehealth encounters are allowed for denominator eligibility regardless of changes in coding or billing practices that may occur. Eligibility of telehealth encounters will be based on the intent of the measure and those settings that are appropriate for inclusion.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

We requested comments on these substantive changes.

As indicated in the introduction to Table Group B of this Appendix, comments on measures that have substantive changes that are not related to what is proposed are considered out of scope and are not included in this final rule. In addition, requested changes on previously finalized measures that were not proposed under the 2026 PFS proposed rule are also out of scope to this final rule. Any potential new substantive changes need to go through notice and comment rulemaking.

D.1 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

	Description
CBE # / eCQM CBE #:	N/A / 0086e
Quality #:	012
CMS eCQM ID:	CMS143v14
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits during the measurement period. **The measure numerator is revised to read:** Patients who have an optic nerve head evaluation during one or more visits during the measurement period.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revising the measure description and numerator by revising the language from “within 12 months" to "during the measurement period" to clarify the timeframe during which an optic nerve head evaluation should be completed. This clarification will ensure the numerator’s quality action is assessed consistently and during the appropriate timeframe.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive change to measure Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33139), we are finalizing the changes to measure Q012 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.2 Advance Care Plan

	Description
CBE # / eCQM CBE #:	0326 / N/A
Quality #:	047
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Substantive Change:	**Modified collection type:** MIPS CQM
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed removing the Medicare Part B Claims collection type as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate, 100 percent, and topped-out status is based on the current MIPS benchmarking data located at https://qpp.cms.gov/benchmarks. However, the benchmarking data continues to show a gap for the MIPS CQM collection type and as such, we proposed retaining that collection type.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters raised concerns about the proposal to remove the Medicare Part B Claims collection type from measure Q047: Advance Care Plan. They noted that eliminating the collection type without adequate support could discourage participation, particularly among small or rural practices without registry access, and risk limiting advance care planning for older adults in rural or underserved areas.

One of the commenters recommended CMS:

- Provide Clear Guidance on Reporting Expectations: Issue updated documentation and educational resources, especially for practices transitioning away from claims-based reporting.
- Support Small and Rural Practices: Explore technical assistance and financial support to help these practices report via MIPS CQMs.
- Ensure Alignment Across Programs: Harmonize the Advance Care Plan measure with other federal programs and private payer initiatives to reduce duplication and burden.
- Monitor Impact and Utility: Track the measure's utility under MIPS CQMs and update as needed to ensure continued relevance and feasibility.

Another commenter also suggested that measure Q047 should move beyond documentation toward goal-concordant care for older adults with multiple chronic conditions.

Response: We thank the commenters for their feedback. Upon further review we agree that removing the Medicare Part B Claims collection type could adversely affect smaller and rural practices. Therefore, we will defer removal of the Medicare Part B Claims collection type. We will take commenter feedback into consideration during the annual MIPS quality measure revisions cycle. We encourage the commenter who suggested updating the measure quality action to reach out to the measure steward to discuss revisions to move measure Q047 toward a more robust, goal-concordant care assessment for possible implementation in future years.

After consideration of public comments, we are not finalizing the changes to measure Q047 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years and will retain the Medicare Part B Claims collection type to support MIPS reporting for smaller and rural practices.

D.3 Diabetes: Eye Exam

	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Modified collection type:** eCQM collection type. **Updated denominator exclusion: For the eCQM collection type: Added:** Exclude patients who have bilateral absence of eyes any time during the patient's history through the end of the measurement period. **The measure numerator is revised to read: For the eCQM collection type:** Patients with an eye screening for diabetic retinal disease. This includes patients with diabetes who had one of the following: - A diagnosis of retinopathy in any part of the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period - No diagnosis of retinopathy in any part of the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period or the year prior to the measurement period - An autonomous eye exam in the measurement period - A retinal exam finding with a retinopathy severity level in any part of the measurement period - A retinal exam finding with no retinopathy severity level in the year prior to the measurement period
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed removing the MIPS CQM collection type as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate, 94.57 percent, and topped-out status is based on the current MIPS benchmarking data located at https://qpp.cms.gov/benchmarks. However, the benchmarking data continues to show a gap for the eCQM collection type and as such, we proposed retaining that collection type. Additionally, for the eCQM collection type, we proposed excluding patients who are missing both eyes as they will not qualify for an eye exam and revising the numerator to allow for an autonomous eye exam to meet the numerator quality action as this is an acceptable standard of care in diabetic patients and will meet measure intent.[624]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter strongly supported revising the numerator of measure Q117: Diabetes: Eye Exam to allow an autonomous eye exam to meet the numerator action. They stated this reflects an accepted standard of care for patients with diabetes, addresses a major complication at the point of care, and aligns with the measure steward's technical specifications. Another commenter supported the updated denominator exclusion and agreed that patients missing both eyes should be excluded, as they would not qualify for an eye exam. The commenter also supported the numerator revision, as an autonomous eye exam is an acceptable standard of care in diabetic patients.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: A commenter strongly opposed removing the MIPS CQM collection type from measure Q117, stressing its importance for ophthalmologists. They warned that eliminating it would negatively affect small and rural ophthalmic practices that often cannot afford CEHRT adoption and therefore cannot report via eCQM. The commenter urged CMS to keep the CQM option to ensure meaningful measurement for ophthalmologists and subspecialists in these settings.

Response: We acknowledge the commenter's concerns, and upon further review, we agree that removing the MIPS CQM collection type could have an adverse impact on small and rural ophthalmic practices. Therefore, we will defer removal of the MIPS CQM collection type. We encourage the commenter to reach out to measure developers/stewards to develop new ophthalmology measures, especially with the MIPS CQM collection type, for submission to the Call for Measures for possible future implementation.

Comment: A commenter was concerned with the revision to allow for an "autonomous eye exam," noting that the language is inaccurate and should clarify that an AI-enabled retinal image is not an eye exam. The commenter emphasized that while AI screenings may help identify risk, only a comprehensive eye exam can evaluate, mitigate, and address those risks, and requested clarification to avoid confusion between AI enabled retinal images and comprehensive eye examinations.

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[624] Wolf, R. M., Channa, R., Lehmann, H. P., Abramoff, M. D., & Liu, T. Y. A. (2024). Clinical Implementation of Autonomous Artificial Intelligence Systems for Diabetic Eye Exams: Considerations for Success. *Clinical Diabetes: A Publication of the American Diabetes Association*, *42*(1), 142–149. https://doi.org/10.2337/cd23-0019.

Response: We thank the commenter for their feedback. This revision aligns with previous updates made to the MIPS CQM collection type, bringing them into alignment. Autonomous AI systems have been approved for use by the FDA beginning in 2018 and was added to the American Diabetes Association's Standards of Medical Care in Diabetes—2019 guidelines.[625] As this technology has grown over time, we determined that eye exams interpreted by an AI system have met the criteria to fill care gaps for value-based care. As such, a CPT code was established to allow for billing and reimbursement using autonomous AI technology to screen and interpret diabetic retinal disease.[626] We encourage the comment to reach out to the measure steward to discuss their concern and suggested revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33140), we are finalizing the changes to the denominator exclusion and measure numerator for measure Q117 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years. We are not finalizing the removal of the MIPS CQM collection type to support MIPS reporting for smaller and rural practices.

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[625] American Diabetes Association (2019). *Standards of Medical Care in Diabetes-2019* Abridged for Primary Care Providers. *Clinical Diabetes: A Publication of the American Diabetes Association*, *37*(1), 11–34. https://doi.org/10.2337/cd18-0105.
[626] See footnote Wolf et al., 2024.

D.4 Documentation of Current Medications in the Medical Record

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	130
CMS eCQM ID:	CMS68v15
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**Updated denominator exception: For the eCQM collection type: Removed:** Medical Reason value set and replaced with "Acute Health Crisis" direct reference code (DRC).
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed replacing the medical reason value set with the Acute Health Crisis DRC for the eCQM collection type as this code better represents the intent of the denominator exception.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to measure Q130: Documentation of Current Medications in the Medical Record.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: A commenter emphasized the importance of ensuring that the new Acute Health Crisis DRC does not inadvertently exclude valid cases where documentation is clinically inappropriate but not emergent. The commenter recommended the following if CMS chooses to replace the medical reason value set with the Acute Health Crisis DRC: preserve flexibility for clinicians; clarify definitions and coding guidance; and monitor impact on performance rates. The commenter also mentioned that this measure remains burdensome and if it is retained and required, it should be required of all clinicians including specialists, not just primary care physicians. The commenter indicated their request to add dental visits to this measure should be considered in future rulemaking.

Response: We thank the commenter for their feedback and acknowledge their concerns. CMS updated this measure to replace the Medical Reason value set with the Acute Health Crisis direct reference code for denominator exceptions to better align with the measure intent, as patients with documented medical reasons such as drug allergy, drug interaction, and drug resistance should be included in the measure. The use of the Acute Health Crisis direct reference code is a more accurate representation of the intent of the exception, as it allows for patients with urgent medical conditions to receive care without medication documentation/reconciliation. With respect to concerns about burden, MIPS eligible clinicians are not required to report this measure, as they have the flexibility to choose measures that are relevant and most meaningful to their practice. This measure is considered cross-cutting and is therefore appropriate and applicable for a broad range of specialties. We appreciate commenter's feedback on opportunities to clarify the measure and will consider providing additional guidance in future iterations of the measure as well as the suggestion to add dental codes, which we will consider for future performance years.

Comment: A commenter supported replacing the medical reason value set with the Acute Health Crisis direct reference code to better represent the denominator exception, but recommended CMS clearly define "Acute Health Crisis." They emphasized the importance of including patients with cognitive or functional limitations in the denominator, as they are at high risk for fragmented care and inappropriate medications. The commenter also highlighted the need for team-based approaches, multi-source verification, and flexible workflows to support these patients and avoid inappropriate exclusions.

Response: We thank the commenter for their support and feedback for the substantive changes. The denominator exception defines 'acute health crisis' as a situation where time is of the essence and delay of treatment would jeopardize the patient's health status. This allows clinicians to use their discretion to determine whether delay of treatment would jeopardize the patient's health status. We recognize that patients with cognitive or functional limits are at higher risk for fragmented care and inappropriate medications. As currently specified, these patients would be included in the measure. We appreciate the commenter's feedback on opportunities to clarify the measure and will consider providing additional guidance in future iterations of the measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33141), we are finalizing the changes to measure Q130 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.5 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	134
CMS eCQM ID:	CMS2v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM

	Description
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Updated guidance: For the eCQM collection type: Revised:** Pharmacological interventions (prescribed or active depression medication). **Revised:** Follow-Up Plan: While there are many validated depression screening tools, they are not necessarily diagnostic tools. Patients with elevated depression screening scores should be followed by a clinician to evaluate whether a depression diagnosis is appropriate, but a medication and/or referral are not always indicated for a positive score. In these cases, a follow up plan is appropriate. **Added:** The measure is not prescriptive in the specific screening tool being used and provides no hierarchy for acceptance of one tool over another. In the case where two screenings are documented on the same date/time with different results (one positive and one negative), the measure only assesses the most recent screening. Since both screenings are both considered the most recent, the patient will be captured in the numerator if the positive screening result also includes documentation of an intervention following the positive screen. **Updated numerator: For the eCQM collection type: Added:** Or an active depression medication overlaps the date of the qualifying encounter.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revising the guidance and numerator for the eCQM collection type to clarify that pharmacological interventions include prescribed or active depression medications. We proposed updating the guidance for determining the appropriate plan of care in instances where the screening tool does not adequately establish a diagnosis of depression. Additionally, we proposed adding guidance to clarify instances of multiple screenings, which aligns with current measure logic. These clarifications will ensure the numerator action is appropriately and consistently assessed.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantive changes to measure Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan. They emphasized the importance of recognizing that many patients receive care outside of the primary care setting and suggested requiring mental and behavioral health providers to document in EHRs and link visits through Health Information Exchanges to improve care coordination. A commenter supported the clarifications, noting the value of accommodating validated screening tools widely used in behavioral health settings and allowing flexibility in documenting follow-up plans. They encouraged CMS to structure the revisions, so they fit seamlessly into existing behavioral health workflows and avoid adding administrative burden.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: A commenter appreciated the revisions to measure Q134, explaining that they ensure clinicians are not penalized when patients screen positive for depression but have alternative causes or triggers, such as thyroid disorders, vitamin deficiencies, unmanaged pain, loneliness, grief, or side effects from medications like beta blockers or glucocorticoids. They emphasized that the follow-up plan for older adults helps ensure these alternative etiologies are properly explored and addressed rather than defaulting to a depression diagnosis. The commenter supported the revised measure for encouraging thorough clinical follow-up and team-based care and urged CMS to provide clear guidance so practices can document when depression screenings are appropriately addressed and accurately report this under the measure.

Response: We thank the commenter for supporting the substantive changes to this measure. The guidance section in the measure specification allows for clinician flexibility and discretion, and provides an example of what would be included in a follow-up plan; however, we will consider further ways to clarify measure guidance in future measure revisions.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33141), we are finalizing the changes to measure Q134 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.6 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care

	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality #:	141
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.
Substantive Change:	**Updated numerator definition: For all collection types: Added:** timing for documenting the plan of care.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed updating the numerator definition for all collection types to clarify the timing of when the care plan must be documented in the patient's medical record after the IOP is assessed. This will ensure timely and optimal patient care and consistent assessment across clinicians for measure performance.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive change to measure Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care.

Response: We thank the commenters for supporting the substantive change to this measure.

Comment: A few commenters requested clarification on the proposal for this measure, as the proposed substantive change was not stated in the rule. The rule states, "Added: timing for documenting the plan of care." However, timing is currently included in the numerator definition as "within the 12-month performance period." While the commenter was able to discuss the intended proposal with the measure steward and has no objections to the change, for most commenters, without a specified proposal, the commenter believed it is impossible to comment on the proposed change for this measure, and therefore no finalized change can be made.

Response: We thank the commenters for supporting the substantive change to this measure and appreciate their feedback. The timeframe for documenting the plan of care is being updated to "within 7 days after the patient encounter when IOP was assessed." Given that the specifics of the substantive change were not clearly outlined in the proposed rule, we are delaying inclusion of the additional language to the measure by 1 year. The delay in measure implementation will improve clinician and system readiness to report the measure. The timeframe allows for different clinical workflows; however, "Completing and signing off on charts within 24-48 hours is a good risk strategy to avoid unfinished charts slipping through the cracks." [627]

After consideration of public comments, we are finalizing the changes to measure Q141 with modification. While we proposed adding timing for documenting the plan of care to the measure for the CY 2026 performance period/2028 MIPS payment year, we are instead finalizing the change with a 1-year delay in implementation. The change will be included in the measure specification for the CY 2027 performance period/2029 MIPS payment year.

[627] Constantine, D. (2025, March 23). *Medical Record Documentation: Time is of the Essence*. The Cooperative of American Physicians. https://www.capphysicians.com/articles/medical-record-documentation-time-essence.

D.7 Oncology: Medical and Radiation – Pain Intensity Quantified

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33142), we are finalizing the changes to measure Q143 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

	Description
CBE # / eCQM CBE #:	0384 / 0384e
Quality #:	143
CMS eCQM ID:	CMS157v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated denominator criteria: For the MIPS CQM collection type: Added:** Patient on oral chemotherapy on or within 30 days before denominator eligible encounter. **Updated guidance: For the eCQM collection type: Removed:** Telehealth from language.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed adding oral chemotherapy to the denominator criteria to align with the eCQM version of the measure that includes SNOMED codes for oral chemotherapy, ensuring that patients on oral chemotherapy are included in the eligible patient population. We proposed removing 'telehealth' from the eCQM guidance to align with coding guidelines for radiation treatment management codes.

D.8 Oncology: Medical and Radiation - Plan of Care for Pain

	Description
CBE # / eCQM CBE #:	0383 / N/A
Quality #:	144
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Substantive Change:	**Updated denominator criteria: Added:** Patient on oral chemotherapy during the performance period.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed adding oral chemotherapy to the denominator criteria to align with the eCQM version of the measure that includes SNOMED codes for oral chemotherapy, ensuring that patients on oral chemotherapy are included in the eligible patient population.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33142), we are finalizing the changes to measure Q144 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.9 Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	176
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions: Added:** new biologic and/or immune response modifiers. - Adalimumab-ryvk (Simlandi), - Rituximab (Rituxan), - Tocilizumab-aazg (Tyenne) - Tocilizumab-bavi (Tofidence), - Ustekinumab (Pyzchiva) - Ustekinumab (Selarsdi) - Ustekinumab (Wezlana) **Revised:** The list of biologic and/or immune response modifier therapies are subject to change as new therapies are approved by the FDA. Newly approved biologic and/or immune response modifier therapies requiring TB testing prior to the first course of therapy would be eligible for inclusion within the Denominator even if not listed above.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed updating the list of medications used in the measure to identify denominator eligible patients by adding new biologic and/or immune response modifiers to the existing list in the denominator instructions. This expansion will provide an up-to-date list of appropriate biologic and/or immune response modifiers that clinicians may have prescribed for their patients, thereby ensuring that as many of the appropriate patients are identified in the denominator of this measure as possible. Additionally, we proposed revising language within the denominator instructions that will clarify the medication list is not exhaustive and any medication that requires TB testing prior to treatment will be appropriate for inclusion.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter requested clarification on the substantive change for measure Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy and that CMS specify whether topical medications should be included in the denominator. As topical biologics and immune modifier therapies do not cause the same increased risk for latent TB reactivation, the commenter specifically requested that CMS explicitly exclude topical medications from this measure.

Response: We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. The measure allows flexibility by only requiring inclusion of therapies that require TB testing prior to initiation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33143), we are finalizing the changes to measure Q176 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.10 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

	Description
CBE # / eCQM CBE #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated denominator exclusion: For the eCQM collection type:** Significant ocular conditions include: Amblyopia, Burn Confined to Eye and Adnexa, Cataract Secondary to Ocular Disorders, congenital cataract, mature or hypermature cataract, posterior polar cataract, central corneal ulcer, certain types of iridocyclitis, choroidal degenerations, choroidal detachment, choroidal hemorrhage and rupture, cloudy cornea, corneal edema, disorders of cornea including corneal opacity, degeneration of macula and posterior pole, degenerative disorders of globe, diabetic macular edema, diabetic retinopathy disorders of optic chiasm, disorders of visual cortex, disseminated chorioretinitis and disseminated retinochoroiditis, focal chorioretinitis and focal retinochoroiditis, glaucoma, hereditary dystrophies (choroidal, corneal, retinal), hypotony of eye, injury to optic nerve and pathways, macular scare of posterior polar, Morgagnian cataract, nystagmus and other irregular eye movements, open wound of eyeball, optic atrophy, optic neuritis, pathologic myopia, posterior lenticonus, prior penetrating keratoplasty, purulent endophthalmitis, retinal detachment with retinal defect, retinal vascular occlusion, retrolental fibroplasias, scleritis, separation of retinal layers, traumatic cataract, uveitis, vascular disorders of iris and ciliary body.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed updating the denominator exclusion for the eCQM collection type to include the list of diagnoses that qualify as significant ocular conditions[628] [629] for the purposes of this measure. This clarification will ensure appropriate patients are consistently identified as denominator eligible and assessed for the numerator action across submitting clinicians for measure performance.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the update to the denominator exclusion for measure Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery to include the list of diagnoses that qualify as significant ocular conditions. While the commenters appreciated the clarification on this measure, they noted that the proposed modification represents a removal of eight exclusionary diagnoses—several of which are related to or specified forms of diagnoses in the current eCQM measure specification.

The commenters urged the maintenance of the following diagnoses in the denominator exclusion: Chronic Iridocyclitis; Glaucoma Associated with Congenital Anomalies and Dystrophies and Systemic Syndromes; Other and Unspecified Forms of Chorioretinitis and Retinochoroiditis; Other Background Retinopathy and Retinal Vascular Changes; Other Disorders of Optic Nerve; Other Endophthalmitis; Other Proliferative Retinopathy; and Visual Field Defects.

Response: We thank the commenters for their feedback. Please note this update does not change the diagnoses included within the value sets for the denominator exclusion. To clarify, the denominator exclusion narrative was shortened due to a new system character limitation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33144), we are finalizing the changes to measure Q191 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[628] Mangione, C. M., Orav, J., Lawrence, M. G., Phillips, R.S., Seddon, J.M., & Goldman, L. (1995). Prediction of Visual Function After Cataract Surgery: A Prospectively Validated Model. *Archives of Ophthalmology, 113*(10), 1305-1311. https://doi.org/10.1001/archopht.1995.01100100093037.

[629] Steinberg, E. P., Tielsch, J. M., Schein, O. D., Javitt, J. C., Sharkey, P., Cassard, S. D., … Damiano, A. M. (1994). National Study of Cataract Surgery Outcomes: Variation in 4-month Postoperative Outcomes as Reflected in Multiple Outcome Measures. *Ophthalmology, 101*(6), 1131-1141. https://doi.org/10.1016/s0161-6420(94)31210-3.

D.11 Dementia: Cognitive Assessment

	Description
CBE # / eCQM CBE #:	N/A / 2872e
Quality #:	281
CMS eCQM ID:	CMS149v14
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period. **Updated guidance: Revised:** The measure requires a diagnosis of dementia be present before the routine assessment of cognition is performed once during the measurement period or the 12 months prior. **The measure numerator is revised to read:** Patients for whom an assessment of cognition is performed and the results reviewed at least once within the 12 months preceding a dementia encounter during the measurement period.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revising the measure description, guidance, and numerator statement to clarify the timing of the routine assessment of cognition and review of the results to ensure that the patient had a diagnosis of dementia at the time of assessment. This revision better aligns with the intent of the measure and will ensure the numerator's quality action is attributable to the denominator eligible criteria.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to measure Q281: Dementia: Cognitive Assessment.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: A commenter supported the clarification to measure Q281, as it aligns the measure more closely with clinical workflows and ensures that assessments are appropriately targeted to patients with a documented diagnosis. However, the commenter urged CMS to consider the documentation burden this clarification may introduce, particularly for small and rural practices and encouraged CMS to provide clear guidance on acceptable documentation formats and workflows to support compliance.

Response: We thank the commenter for their feedback. The intent of the revision is to ensure that a diagnosis of dementia was present at the time of cognitive assessment. MIPS eligible clinicians have the flexibility to determine how they document and review the results. The measure specification includes definitions and guidance for measure implementation. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: A commenter requested clarification on the substantive changes proposed for measure Q281. It is unclear whether assessment is one-time or annual; annual cognitive testing in diagnosed dementia seems unnecessary. There is uncertainty about whether measure intends to use global staging tools (for example, FAST, CDR) vs. serial cognitive tests (for example, MoCA, SLUMS).

The commenter supported yearly documentation of dementia stage when appropriate but cautioned against routine annual cognitive testing, which may not change care management. The commenter stated that assessment decisions should be individualized, patient-centered, and guided by clinical judgment; tracking decline should be linked to actionable care planning, caregiver support, and community resources.

Response: We thank the commenter for their feedback and encourage them to reach out to the measure steward to discuss revisions for possible implementation in future years. Cognitive deterioration, defined by continuous decline, has been identified as a major source of morbidity and mortality,[630] [631] making it necessary for clinicians to perform ongoing assessments to develop or modify the patient's treatment plan as well as monitor the effects of the treatment. As currently specified, the measure requires a cognitive assessment to be performed at least once within the 12 months preceding a dementia encounter. The measure does not require the use of a specific tool and allows for clinician judgement, and the requirement for two denominator eligible encounters ensures patient-clinician relationship.

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[630] van den Kieboom, R., Snaphaan, L., Mark, R., & Bongers, I. (2020). The Trajectory of Caregiver Burden and Risk Factors in Dementia Progression: A Systematic Review. *Journal of Alzheimer's Disease : JAD*, *77*(3), 1107–1115. https://doi.org/10.3233/JAD-200647.

[631] Lanctôt, K. L., Hviid Hahn-Pedersen, J., Eichinger, C. S., Freeman, C., Clark, A., Tarazona, L. R. S., & Cummings, J. (2024). Burden of Illness in People with Alzheimer's Disease: A Systematic Review of Epidemiology, Comorbidities and Mortality. *The Journal of Prevention of Alzheimer's Disease*, *11*(1), 97–107. https://doi.org/10.14283/jpad.2023.61.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33145), we are finalizing the changes to measure Q281 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.12 Surgical Site Infection (SSI)

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	357
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older who had a surgical site infection (SSI).
Substantive Change:	**Updated instructions: Added:** All sites of the primary procedure and integral procedures performed during that trip to the operating room should be evaluated as part of this measure for possible wound occurrences. If more than one SSI is observed, assign the SSI at the deepest level (superficial, deep or organ/space) that occurs within a 30-day postoperative timeframe.
Measure Steward:	American College of Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed updating the measure instructions to clarify how to handle multiple procedures during a single encounter. By assigning the SSI at the deepest level (superficial, deep, or organ/space) in situations where more than one SSI is observed within a 30-day postoperative timeframe, the most adverse surgical outcome is captured as an indicator of the quality of care provided.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed substantive changes to measure Q357: Surgical Site Infection (SSI).

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33145), we are finalizing the changes to measure Q357 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.13 Closing the Referral Loop: Receipt of Specialist Report

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	374
CMS eCQM ID:	CMS50v14
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.
Substantive Change:	**Updated guidance: For the eCQM collection type: Added:** A procedural report received from a specialist for an exam or procedure conducted (e.g., diabetic eye exam, colonoscopy) can satisfy the numerator requirement and successfully close the referral loop. A separate consultant note or consultant report is not required to close the referral loop in these circumstances. **The measure numerator is revised to read: For the eCQM collection type:** Number of patients with a referral on or before October 31, for which the referring clinician received a report from the first clinician to whom the patient was referred.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed updating the guidance and numerator for the eCQM collection type to align with current measure logic, which requires a report from the referral. These updates allow for improved electronic implementation of the measure.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter strongly supported CMS' proposed substantive changes to measure Q374: Closing the Referral Loop: Receipt of Specialist Report. The commenter appreciated the clarification that procedural reports, such as diabetic eye exams and colonoscopies, meet numerator requirements and close the referral loop. The commenter also highlighted the growing role of AI-supported retinal imaging in primary care and stressed that recognizing these reports reflects clinical practice and reduces burden.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: A commenter appreciated CMS' efforts to revise the eCQM's guidance and numerator to align with current measure logic. The commenter continued to have concerns with this measure in general: it inappropriately holds primary care clinicians accountable for patient or subspecialist actions, for example, patients may not pursue referrals or subspecialty clinics may fail to send reports back.

Response: We acknowledge the commenter's concerns. The intent of this measure is to encourage communication between the referring clinician and the clinician to whom the patient is referred to ultimately improve health outcomes for the patient.[632] However, as noted in the measure specification, a report to the referring clinician stating that the patient did not attend the appointment will suffice for performance met. While the measure's quality action does rely on a feedback loop, it is also incumbent upon the referring clinician to ensure adequate care pathways and communication between clinicians, thus ensuring the referring clinician has all the information needed to treat the patient appropriately.

Comment: A few commenters supported the updated guidance for the measure and agreed that in the case of a procedure or exam (for example, diabetic eye exam), a procedural report from the specialist is sufficient to close the referral loop. However, the commenters opposed the numerator revision requiring the referring clinician to receive a report from the first clinician to whom the patient was referred. Patients may choose to see a different clinician within the same specialty (other than the one to whom they were initially referred), or it may be necessary for the patient to see a different specialist or subspecialist altogether. The commenters stated there are numerous reasons why requiring the referring clinician to receive a report from the first clinician would not be practical or appropriate.

Response: The intent of the measure is to ensure that the referral loop is closed; it does not require that a specific clinician complete the report, only that the report received is associated with the denominator eligible referral in the medical record. Patients who receive a referral to a specific specialist may choose to see an alternate clinician/practice; however, it is essential they are still being appropriately assessed for the medical issue they were referred for. The alternate clinician/practice's report would suffice for the numerator, closing the referral feedback loop.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33146), we are finalizing the changes to measure Q374 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[632] Patel, M. P., Schettini, P., O'Leary, C. P., Bosworth, H. B., Anderson, J. B., & Shah, K. P. (2018). Closing the Referral Loop: An Analysis of Primary Care Referrals to Specialists in a Large Health System. *Journal of General Internal Medicine*, *33*(5), 715–721. https://doi.org/10.1007/s11606-018-4392-z.

D.14 Functional Status Assessment for Total Hip Replacement

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v14
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.
Substantive Change:	**Updated denominator exclusion: Revised:** Exclude patients with one or more specific lower body fractures indicating trauma in the 48 hours before or at the start of the total hip arthroplasty.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed updating the denominator exclusion regarding one or more specific lower body fractures by increasing the timeframe to 48 hours prior to the start of THA. Trauma occurring in the 48 hours leading up to a total hip replacement can potentially affect the outcome of the surgery, depending on factors such as the severity of the trauma or the need to stabilize and/or adequately assess the condition of the patient. This extended timeframe will ensure patients undergoing THA are prepared for the procedure and not in an emergent situation.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the substantive changes to measure Q376: Functional Status Assessment for Total Hip Replacement to update the denominator exclusion regarding one or more specific lower body fractures indicating trauma.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33146), we are finalizing the changes to measure Q376 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.15 Cataract Surgery: Difference Between Planned and Final Refraction

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	389
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.
Substantive Change:	**Updated numerator note: Added:** It would be expected that the planned (target) refraction be assessed and documented within 90 days prior to the denominator eligible procedure.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed adding a numerator note to the measure, which will ensure that only those patients with recently obtained planned (target) refractions are considered for numerator compliance. As refractions may change over time, it is essential that patients undergoing cataract surgery have current and accurate results for appropriate ophthalmic evaluations, which will be used by the ophthalmologist to counsel the patient about target postoperative refractive options and formulation of a care plan that will achieve the documented target refraction.[633]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed substantive change to measure Q389: Cataract Surgery: Difference Between Planned and Final Refraction.

Response: We thank the commenter for supporting the substantive change to this measure.

Comment: A few commenters supported the proposed change to this measure with modification and agreed that the measure should only include those patients with recently obtained planned refractions. The commenters requested that clinicians have the option of assessing and documenting the planned refraction on the day of the procedure, not just within 90 days prior to the procedure.

Response: We thank the commenters for supporting the substantive change to this measure and note that the timing does not exclude refractions taken on the day of the procedure, only that it must be completed within 90 days prior to the procedure. The intent is to ensure recent target refractions are being utilized to assess numerator compliance.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33147), we are finalizing the changes to measure Q389 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

[633] Miller, K. M., Oetting, T. A., Tweeten, J. P., Carter, K., Lee, B. S., Lin, S., Nanji, A. A., Shorstein, N. H., Musch, D. C., & American Academy of Ophthalmology Preferred Practice Pattern Cataract/Anterior Segment Panel (2022). Cataract in the Adult Eye Preferred Practice Pattern. *Ophthalmology*, *129*(1), P1–P126. https://doi.org/10.1016/j.ophtha.2021.10.006.

D.16 Immunizations for Adolescents

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	394
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.
Substantive Change:	**The measure description is revised to read:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday. **The measure numerator is revised to read: For Submission Criteria 1:** Adolescents who had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B) on or between the patient's 10th and 13th birthdays. **Updated numerator options: Revised: For Submission Criteria 1:** **Performance Met:** Patient had one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B) on or between the patient's 10th and 13th birthdays. **Performance Not Met:** Patient did not have one dose of meningococcal vaccine (serogroups A, C, W, Y or A, C, W, Y, B), on or between the patient's 10th and 13th birthdays.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revising the measure description and numerator to add the pentavalent serogroup meningococcal vaccine as numerator compliant for patients for which it is suggested. This update reflects recommendations of the CDC Advisory Committee on Immunization Practices that children may receive pentavalent vaccine starting at age 10 (https://www.cdc.gov/mmwr/volumes/73/wr/mm7315a4.htm).

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposal to incorporate the pentavalent meningococcal vaccine into the measure. The commenter encouraged CMS to continue investing in immunization information systems modernization and data exchange infrastructure to support accurate measure reporting.

Response: We thank the commenter for their feedback.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33148), we are finalizing the changes to measure Q394 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.17 Osteoporosis Management in Women Who Had a Fracture

	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.
Substantive Change:	**The measure numerator note is revised to read: For all collection types:** For the purposes of submitting this measure, Central Dual Energy X-Ray Absorptiometry (DXA), the most common measurement for measuring bone mineral density (BMD), spinal densitometry X-ray, and Peripheral Dual-energy X- Ray Absorptiometry (DXA) would meet performance and the intent of the measure. Therefore, 3095F would be submitted in the instances those screening modalities are utilized.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed revising the list of tests for measuring BMD by removing CT bone density axial and ultrasonography for densitometry as meeting performance. These changes will ensure testing required for numerator compliance is better aligned with guidelines and best practices.[634]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed revisions to the numerator note to measure Q418: Osteoporosis Management in Women Who Had a Fracture.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: Several commenters opposed the proposed change to measure Q418, urging CMS not to restrict access to CT-based bone mineral density (BMD) tests such as BCT and QCT. They emphasized that these modalities are FDA-cleared, clinically effective, safe, convenient, and in some cases more accessible for patients who have already undergone CT imaging for other reasons, particularly fracture patients who may find it difficult to obtain a new DXA scan. Commenters noted that BCT is at least as safe and effective as DXA, does not require DXA confirmation, and is particularly suitable for patients who recently had hip or spine CTs. They warned that excluding CT-based tests would inexplicably eliminate innovative and validated options, depriving Medicare beneficiaries of convenient and effective care while unfairly penalizing clinicians.

A commenter further highlighted that DXA access is already limited, with reduced reimbursement rates, fewer available scanners, and some patients waiting up to six months post-fracture for a 20-minute scan. The commenter stressed that QCT and BCT both meet validation requirements for bone density and will likely see increased use with the growth of artificial intelligence technologies. Another commenter underscored that removing CT from measure Q418 would undermine patient care and urged CMS to keep all validated BMD testing modalities included in the measure to ensure broad patient access and preserve clinical flexibility.

Response: We thank the commenters for their feedback. As noted in the rationale, clinical guidelines and best practices, including USPSTF recommendations for osteoporosis screening,[635] have shown that DXA is a more effective tool, in terms of focus and cost, for measuring BMD. Although BCT has its benefits in certain instances, it is "well suited for opportunistic use in a patient who is already undergoing a hip- or spine-containing CT for other purposes" and not best suited for monitoring a patient's response to treatment,[636] whereas DXA has lower radiation exposure, is considered to be more accurate for diagnosing osteoporosis and monitoring treatment, and more cost effective. We also note that the codes for BCT and QCT are not currently covered by Medicare for ongoing treatment monitoring.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33149), we are finalizing the changes to measure Q418 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

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[634] USPSTF. (2025). Osteoporosis to Prevent Fractures: Screening. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/osteoporosis-screening.

[635] See USPSTF, 2025.

[636] Keaveny, T. M., Clarke, B. L., Cosman, F., Orwoll, E. S., Siris, E. S., Khosla, S., & Bouxsein, M. L. (2020). Biomechanical Computed Tomography Analysis (BCT) for Clinical Assessment of Osteoporosis. *Osteoporosis International: A Journal Established as Result of Cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA, 31*(6), 1025–1048. https://doi.org/10.1007/s00198-020-05384-2.

D.18 Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	420
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.
Substantive Change:	**The measure denominator is revised to read:** All patients who are treated for varicose veins with saphenous ablation and who receive an outcomes survey within 180 days after treatment. **The measure numerator is revised to read:** Patients whose outcome survey score improved when assessed within 180 days following treatment. **Updated numerator options: Added:** Denominator Exception: Documentation of at least two attempts to follow up with patient within 180 days of treatment Performance Not Met: No documentation of at least two attempts to follow up with patient within 180 days of treatment Performance Not Met: Patient follow up more than 180 days after treatment **Removed:** Denominator Exception: Patient survey results not available
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed updating the measure's timeframe for assessing patient outcomes to anytime within 6 months following the treatment. While the ideal assessment time is 3-6 months following the treatment, trials have shown improvement occurred fairly quickly before slowing and plateauing at about six months.[637] Therefore, it is reasonable a patient may show improved scores sooner than 3 months, and this revision will allow flexibility in workflow while ensuring quality outcomes are achieved. Additionally, we also proposed updating the numerator options to ensure patients were not lost to follow-up without a reasonable attempt made. By replacing the exception for patient survey results not available, we will require documentation that the patient was actively sought for follow-up.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33150), we are finalizing the changes to measure Q420 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

[637] Gibson, K., Morrison, N., Kolluri, R., Vasquez, M., Weiss, R., Cher, D., Madsen, M., & Jones, A. (2018). Twenty-four Month Results from a Randomized Trial of Cyanoacrylate Closure Versus Radiofrequency Ablation for the Treatment of Incompetent Great Saphenous Veins. *Journal of Vascular Surgery. Venous and Lymphatic Disorders*, *6*(5), 606–613. https://doi.org/10.1016/j.jvsv.2018.04.009.

D.19 Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	441
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated
Substantive Change:	**The measure description is revised to read:** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • High Intensity Statin Use Unless Contraindicated **Updated denominator criteria: Removed:** coding for arterial embolism and thrombosis from CAD Risk-Equivalent Conditions. **The measure numerator is revised to read: For all Submission Criteria:** The number of IVD patients who meet ALL of the following targets: • Most recent BP is less than or equal to 130/80 mm Hg • Most recent tobacco status is Tobacco Free (NOTE: If there is No Documentation of Tobacco Status the patient is not compliant for this measure) • Daily Aspirin or Other Antiplatelet Unless Contraindicated • High Intensity Statin Use Unless Contraindicated **Updated numerator note: Added: For all Submission Criteria: Component 4:** Valid High Intensity statins include Atorvastatin 40-80 mg and Rosuvastatin 20-40 mg. **Updated numerator options: Revised: For all Submission Criteria:** **Component 1:** require blood pressure to be less than or equal to 130/80 mm Hg. **Component 4:** require use of high intensity statin therapy.
Measure Steward:	Wisconsin Collaborative for Healthcare Quality
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed updating multiple components of this measure to align with the AHA/ACC/ACCP/ASPC/NLA/PCNA Guidelines (https://www.ahajournals.org/doi/10.1161/CIR.0000000000001168). We proposed revising normal blood pressure measurement from 140/90 to 130/80 and switch from Statin Use Unless Contraindicated to High Intensity Statin Use Unless Contraindicated. Given that the diagnoses included in the measure represent the highest level of cardiovascular risk, and given current guidelines, the measured population is best served by being held to a lower blood pressure measurement and by being on a high-intensity statin to reduce the risk of a major cardiac event. We also proposed removing coding for arterial embolism and thrombosis from the CAD Risk-Equivalent Conditions denominator criteria as these conditions do not share the same pathophysiology or treatment goals and therefore misalign with the intent of the measure.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments received and our responses.

Comment: A few commenters supported CMS' efforts to align measure Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) with updated clinical guidelines, including the tighter blood pressure target and use of high-intensity statins. However, both expressed concerns that the "all-or-none" structure could disproportionately penalize clinicians for missed documentation, patient non-adherence, or a single unmet component, even when most care goals are achieved. They emphasized that this approach could be especially burdensome for small and rural practices or those serving high-risk populations with limited health IT infrastructure. Commenters recommended alternatives such as scoring individual components, stratified composites, or averaging blood pressure over time, and highlighted the need for technical assistance, EHR integration support, and appropriate attribution in multispecialty settings with shared accountability. They urged CMS to monitor for unintended consequences while preserving alignment with evidence-based guidelines.

Response: We thank the commenters for their feedback and encourage them to reach out to the measure steward to discuss revisions for possible implementation in future years. We also acknowledge that due to nuances in clinician specialization, scope

of care, or regional location, not all measures within MIPS will be applicable or appropriate to all clinicians within that specialty set umbrella. MIPS provides clinician choice to account for these nuances, while ensuring clinicians can choose measures that are most meaningful to their scope of care and patient case-mix. This measure uses an “all-or-none” analytic as it’s important that IVD patients meet all of these standards to drive the best possible outcomes.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33151), we are finalizing the changes to measure Q441 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.20 Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer

	Description
CBE # / eCQM CBE #:	1858 / N/A
Quality #:	450
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.
Substantive Change:	**Updated denominator criteria: Revised:** AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis = T1c. **Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed revising the denominator criteria for T-stage breast cancer to ensure patients with T1mic, TX, T0 and Tis are not inadvertently included in the denominator eligible population as HER2-targeted therapy is typically not indicated.[638] [639] We also proposed adding a denominator note to clarify the encounter requirement to require and reflect two separate encounters occurring on different days with the same reporting provider or group.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33152), we are finalizing the changes to measure Q450 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

[638] American Joint Committee on Cancer. (2010). AJCC Cancer Staging Manual. https://www.facs.org/media/kwupoct5/ajcc-7th-ed-cancer-staging-manual.pdf.

[639] Johnson, K. C., Quiroga, D., Sudheendra, P., & Wesolowski, R. (2022). Treatment of Small (T1mic, T1a, and T1b) Node-negative HER2+ Breast Cancer - A Review of Current Evidence For and Against the Use of Anti-HER2 Treatment Regimens. *Expert Review of Anticancer Therapy*, *22*(5), 505–522. https://doi.org/10.1080/14737140.2022.2063844.

D.21 RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

	Description
CBE # / eCQM CBE #:	1859 / N/A
Quality #:	451
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.
Substantive Change:	**Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters, and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed adding a denominator note to clarify the encounter requirement to require and reflect two separate encounters occurring on different days with the same reporting provider or group.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33153), we are finalizing the changes to measure Q451 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.22 Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)

	Description
CBE # / eCQM CBE #:	0210 / N/A
Quality #:	453
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.
Substantive Change:	**Updated denominator criteria: Added:** coding to allow telehealth as denominator eligible. **Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed adding telehealth coding as denominator eligible for this measure as it is appropriate for patients seen via telehealth to be included in the denominator for assessment of performance. We also proposed adding a denominator note to clarify implementation of the denominator criteria encounter requirement, which will ensure the denominator eligible patient population is appropriately identified and consistent across clinician submissions.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33153), we are finalizing the changes to measure Q453 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.23 Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)

	Description
CBE # / eCQM CBE #:	0216 / N/A
Quality #:	457
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.
Substantive Change:	**Updated denominator criteria: Added:** coding to allow telehealth as denominator eligible. **Updated denominator note: Added:** The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed adding telehealth coding as denominator eligible for this measure as it is appropriate for patients seen via telehealth to be included in the denominator for assessment of performance. We also proposed adding a denominator note to clarify implementation of the denominator criteria encounter requirement, which will ensure the denominator eligible patient population is appropriately identified and consistent across clinician submissions.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (90 FR 33154), we are finalizing the changes to measure Q457 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.24 Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

	Description
CBE # / eCQM CBE #:	3493 / N/A
Quality #:	480
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.
Substantive Change:	**Updated denominator exclusion: Removed:** COVID exclusion
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed excluding admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominator due to the end of the public health emergency (PHE). This change aligns this measure with language finalized under the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule (90 FR 36948 through 36950).

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments received and our responses.

Comment: A commenter did not support the substantive changes to measure Q480: Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) to remove the denominator exclusion for patients with either a principal or secondary diagnosis of COVID–19 present on admission.

Response: We thank the commenter for their feedback. Given the end of the federal COVID–19 PHE on May 11, 2023, it is important to provide physicians and beneficiaries with a complete picture of the care quality provided for all patients. Because this measure includes elective procedures, surgeons would opt to operate on relatively healthy patients and would not (or should not) select patients with active COVID-19. While hospitals and other types of health care facilities may face continuing challenges due to the long-term effects of the COVID–19 PHE, we do not agree these challenges represent such a significant threat to health care operations that patients with a principal or secondary COVID–19 diagnosis should be excluded from the MIPS THA/TKA Complication measure cohort. Additionally, in testing data, less than five hundredths of a percent (0.04%) of patients were excluded from the measure due to having a COVID-19 diagnosis, also showing a decline in the number of patients excluded from the measure cohort. Removing the exclusion of COVID–19 patients is intended to ensure that the measure continues to account for outcomes as intended and to meet the goals of MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33154), we are finalizing the changes to measure Q480 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.25 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC)

	Description
CBE # / eCQM CBE #:	3597 / N/A
Quality #:	484
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	The measure is a risk-standardized rate of acute, unplanned hospital admissions for the Merit-based Incentive Payment System (MIPS) among Medicare Fee-for-Service (FFS) patients aged 65 years and older with multiple chronic conditions (MCCs); i.e., two or more of nine qualifying chronic conditions. The measure is adjusted for age, chronic condition categories, and other clinical and frailty risk factors present at the start of the 12-month measurement period as well as social risk factors. The measure attributes admissions to MIPS participating clinicians and/or clinician groups, as identified by their National Provider Identifiers (NPIs) and/or Taxpayer Identification Number (TIN) and assesses each clinician's or clinician group's admission rate.
Substantive Change:	**Update denominator exclusion: Remove**: Patients assigned to clinician who achieve Qualifying Advanced Alternative Payment Model Participant (QP) status and therefore do not participate in MIPS.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed revising the denominator eligible patient population by removing the denominator exclusion regarding QP status. When the MIPS MCC measure was proposed in the CY 2022 PFS proposed rule (86 FR 39270 through 39271) and finalized in the final rule (86 FR 65264 through 65265), there was a parallel proposal to remove the ACO MCC measure from the Medicare Shared Saving Plan (SSP) APM Performance Pathway (APP) measure set and replace it with the MIPS MCC measure. With a MIPS measure now in place, and consistent with the initial intent, we proposed removing this exclusion to broaden the scope of the measure and account for all MIPS participants, particularly those in APM entities who may have QP status.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to measure Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC).

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: A few commenters had concerns about this measure and did not support the proposed change to the measure specifications to remove the exclusion for anyone with a QP status from the measure. One of the commenters recommended that CMS retain the QP exclusion for this measure, warning that its removal could distort benchmarking and unfairly hold MIPS clinicians accountable for patients managed under different care models. They raised concerns about duplicative accountability for clinicians participating in both APMs and MIPS subgroups and emphasized the need for refined attribution that reflects shared care between primary and specialty clinicians. The commenter also urged CMS to distinguish preventable from non-preventable admissions and ensure transparent risk adjustment, particularly for cardiologists treating complex patients. They concluded that the QP exclusion should remain until a comparable attribution approach is developed for QPs.

The commenters noted that the attribution methodology varies significantly across important MIPS and MVP quality measures, such as measure Q479: Hospital-wide, 30-Day, All-cause Unplanned Readmission (HWR) Measure for the Merit-based Incentive Payment System (MIPS) Groups and measure Q484. This variation in methodologies (for example, plurality of charges vs. plurality of visits) can result in different physicians being accountable for different, but related measures. Commenters believed the lack of a cohesive approach to attribution within MIPS is not sustainable and must be addressed to create a system that promotes and facilitates meaningful and actionable feedback to physicians. One of the commenters stated that consistent, predictable, and actionable feedback provided in a timely manner will ultimately help CMS achieve its primary goal of achieving better care for its beneficiaries.

Response: We thank the commenters for their feedback. QPs are exempt from MIPS based on eligibility assessments during snapshot periods. Additionally, reporting pathways are different between MIPS and APM performance pathways and each individual pathway has published benchmarks. As such we will continue to monitor performance and areas where benchmarking is potentially penalizing any specific group. Ultimately the shared goal across payment pathways is to provide and incentivize high quality care. It is also important to note that other measures included in the MIPS programs do not currently exclude QPs and hence the removal of this exclusion brings this measure into alignment with the MIPS program as a whole. As noted in the proposed rule, the original reason for this exclusion was to account for the ACO MCC measure which is now being replaced by this measure. CMS also recognizes the importance of comprehensive and transparent risk adjustment, and the current measure already includes adjustments for patient complexity to address differences in patients seen by cardiologists including specific adjustors for pulmonary heart disease and heart rhythm disorders alongside numerous other clinical and social risk factors. The removal of the QP status exclusion will not change this.

We appreciate the concern for consistency across measures in the MIPS program and will continue to consider refinements to specifications to address concerns about alignment. The differences in attribution between this measure and Q479 are based on considerations specific to this measure and especially on the units of attribution being patients as opposed to hospital stays, with the goal in this measure being to identify the clinician most responsible for a patient's care over the course of a long performance

period. These measures capture different aspects of patient care and are not duplicative for providers who may be scored on both measures.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33155), we are finalizing the changes to measure Q484 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.26 Kidney Health Evaluation

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	488
CMS eCQM ID:	CMS951v4
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.
Substantive Change:	**Updated guidance: For the eCQM collection type: Added:** The Urine Albumin-Creatinine Ratio (uACR) requirement can be met with a documented Urine Albumin and Urine Creatine less than or equal to four days apart. A calculation of uACR is not required to meet this measure, but it is intended to for the uACR to be calculated for the purposes of kidney health evaluation. If the Urine Albumin and Urine Creatine tests have different units of measure, they should be converted to the same unit of measure for the purposes of calculating uACR. The Urine Albumin Creatinine Ratio Test requirement can be met if the lab result is received as a quantitative value or as an undetectable result. Undetectable results can be coded using values in the "Undetectable Lab Result Value" value set. **The measure numerator is revised to read: For the eCQM collection type:** Patients who received a kidney health evaluation during the measurement period. Kidney health evaluation is defined by an eGFR AND uACR within the measurement period OR an eGFR and a Urine Albumin and Urine Creatine result documented less than or equal to four days apart.
Measure Steward:	National Kidney Foundation
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed updating the guidance and the numerator for the eCQM collection type to clarify how the uACR requirement may be met in instances where the lab results are non-quantitative, that is, undetectable or the Urine Albumin and Urine Creatine tests are run separately. This will ensure the measure logic is appropriately assessing clinicians as numerator compliant when the intent of the measure has been met.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: For measure Q488: Kidney Health Evaluation, a commenter urged CMS to address the technical issue regarding the undetectable uACR values to remove the suppression from future performance years starting in PY 2026 and offered support in this effort if CMS pursues to address the issue. Another commenter supported the proposed changes for this measure.

Response: We thank the commenters for supporting the substantive changes to this measure. The guidance proposed to be added is clarifying information on how the uACR requirement may be met in instances where the lab results are non-quantitative or undetectable. This will allow proper and consistent implementation of the measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33156), we are finalizing the changes to measure Q488 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.27 Adult Immunization Status

	Description
CBE # / eCQM CBE #:	3620 / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B**.** **Updated instructions:** **Added:** Performance Rate 5 for reporting of hepatitis B vaccine series. **Revised:** Percentage of patients (50 years of age and older on the date of the encounter) who received 2 doses of the herpes zoster recombinant vaccine anytime on or after the patients' 50th birthday. **Updated denominator: Added: Submission Criteria 5:** Patients 19 years of age or older on the date of the encounter with a visit during the measurement period. **Updated denominator criteria: Added: Submission Criteria 5:** Patients age 19 and older on the date of the encounter AND Patient encounter during the performance period AND NOT DENOMINATOR EXCLUSION: In hospice or using hospice services during the measurement period. **Updated numerator: Revised: Submission Criteria 3:** Patients in Denominator 3 who received 2 doses of the herpes zoster recombinant vaccine on October 20, 2017, through the end of the measurement period. **Added: Submission Criteria 5:** Patients in Denominator 5 who were administered a hepatitis B vaccine series on or after their 19th birthday and before the end of the measurement period. **Updated numerator instructions: Added: Submission Criteria 5:** In order to meet criteria for this numerator, patients must have one of the following: 1) at least three doses of the childhood hepatitis B vaccine with different dates of service on or before their 19th birthday; 2) at least two doses of the recommended two-dose adult hepatitis B vaccine administered at least 28 days apart; 3) at least three doses of any other recommended adult hepatitis B vaccine administered on different dates of service; and 4) received a hepatitis B surface antigen, hepatitis B surface antibody, or total antibody to hepatitis B core antigen test with a positive result. **Updated numerator note: Added: Submission Criteria 5:** Patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator. **Updated numerator options: Revised: Submission Criteria 3:** **Performance Met:** Patient received at least two doses of the herpes zoster recombinant vaccine (at least 28 days apart) on October 20, 2017, through the end of the measurement period. **Performance Not Met:** Patient did not receive two doses of the herpes zoster recombinant vaccine (at least 28 days apart) on October 20, 2017, through the end of the measurement period. **Added: Submission Criteria 5:** **Performance Met:** Patient received recommended doses of hepatitis B vaccination based on age. **Denominator Exception:** Patient has a history of hepatitis B illness or received a hepatitis B surface antigen, hepatitis B surface antibody, or total antibody to hepatitis B core antigen test with a positive result any time before or during the measurement period. **Denominator Exception:** Documentation of medical reason(s) for not administering hepatitis B vaccine (e.g., prior anaphylaxis due to the hepatitis B vaccine). **Denominator Exception:** Documentation that patient is a Medicare Fee-For-Service beneficiary and without additional supplementary insurance coverage for whom Hep B vaccination is not reimbursable under current Medicare Part B coverage rules. **Performance Not Met:** Patient did not receive recommended doses of hepatitis B vaccination based on age.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process

	Description
Rationale:	We proposed revising the measure to include the Hepatitis B vaccine in the list of routine vaccinations of adults aged 19 years and older based on updated recommendations of the Advisory Committee on Immunization Practices. The literature shows that approximately 50 percent of acute hepatitis B cases reported in 2019 occurred among persons aged 30–49 years due to low Hep B vaccination coverage among adults aged greater than or equal to 9 years. Furthermore, an estimated 2 percent to 6 percent of acute hepatitis B viral infections have been found to lead to chronic hepatitis B among adults (https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm). In the event the proposed substantive change(s) were finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

We note that under the substantive changes row, for the **Updated numerator: Revised: Submission Criteria 3,** the date has been revised from October 1, 2017 (90 FR 33157) to October 20, 2017, to align with the measure specifications and ACIP approval date.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to measure Q493: Adult Immunization Status. One of the commenters requested that if the proposed changes to measure Q493 are finalized and a new benchmark is created, that CMS apply the 7-point scoring floor used for first-year MIPS measures.

Response: We thank the commenters for supporting the substantive changes to this measure. There are policies in place that address when a 7-point score floor is applied, which does not include benchmark removal due to substantive changes. However, we will take the recommendation under advisement. While the measure data is not directly comparable, implementation of the measure in MIPS has been established. Therefore, the measure does not meet the intent of the 'new measure' scoring policy, which is to incentivize adoption of new MIPS measures.

Comment: A commenter did not support the proposed substantive changes to include the Hepatitis B vaccine for adults aged 19 and older in measure Q493. The commenter noted that many adults were vaccinated in childhood, but records are often unavailable, and immunization registries remain fragmented and inconsistent. They questioned whether clinicians would be required to order costly serologic titers or retrieve decades-old records, warning this could create financial and workflow burdens—particularly harming underserved populations. The commenter recommended CMS delay implementation until interoperability and registry functionality improve, ensure full coverage of titers if required for compliance, provide clear guidance on acceptable documentation sources and workflow, and monitor for unintended consequences, including over-testing or unnecessary repeat vaccinations.

Response: We thank the commenter for their feedback. As noted above, "Patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator." In addition, there are denominator exceptions for the Hepatitis B vaccine that address certain scenarios for not receiving a given vaccine.

Comment: A commenter appreciated CMS' proposal to add the Hepatitis B vaccine to the list of routine vaccinations in measure Q493, noting its relevance for certain at-risk older adults. However, they expressed concern about financial barriers for tetanus, diphtheria, pertussis, and zoster vaccines, which are often not covered for Medicare beneficiaries. They emphasized that the high cost, especially for the zoster vaccine, leads many older adults to forgo vaccination. The commenter recommended that CMS ensure immunizations are affordable for all Medicare beneficiaries and that providers receive appropriate payment.

Response: We acknowledge that there are sometimes system reasons for not completing a quality action and account for those as appropriate; however, patients who choose not to receive a vaccine would be distributed across clinicians, affecting all reporting this measure. We allow clinician choice in measures to report, ensuring clinicians can choose measures that are most meaningful to their scope of care and patient case-mix.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33157 through 33158), we are finalizing the changes to measure Q493 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

D.28 Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	500
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Substantive Change:	**Updated Instructions: Revised:** This measure is to be submitted once per performance period for acute PVD in either eye. For the purpose of submitting this measure, only unique occurrences with an onset of acute PVD diagnosed within the current performance period will be denominator eligible, with the most recent occurrence (if there is more than one occurrence) being used for performance calculation.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed updating the measure submission frequency to once per performance period as simultaneous or very close-in-time bilateral PVDs are rare.[640] In the event the proposed substantive change(s) were finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed substantive changes to measure Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up. The commenter recommended CMS finalize the proposed changes to clarify the measure should be reported once per performance period. The commenter appreciated the assistance and input from CMS througout the developmene of this measure.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: A few commenters requested that if the proposed changes to measures Q500 and Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up are finalized, and new benchmarks are created that CMS apply the 7-point scoring floor used for first-year MIPS measures. This would be appropriate for these measures, given the substantive changes resulting in no direct comparison to previous benchmarks. The commenter stated it is also important to avoid disincentivizing the reporting of two important measures, which would functionally reduce the already limited pool of measures available to ophthalmologists.

Response: We thank the commenters for their feedback. There are policies in place that address when a 7-point score floor is applied, which does not include benchmark removal due to substantive changes. However, we will take the recommendation under advisement. While the measure data is not directly comparable, implementation of the measure in MIPS has been established and therefore does not meet the intent of the 'new measure' scoring policy, which is to incentivize adoption of new MIPS measures.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33159), we are finalizing the changes to measure Q500 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

[640] Retina Specialist. (2021). Five Evidence-based Answers for PVD, Retinal Breaks. https://www.retina-specialist.com/article/five-evidencebased-answers-for-pvd-retinal-breaks.

D.29 Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	501
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.
Substantive Change:	**Updated Instructions: Revised:** This measure is to be submitted once per performance period for acute PVD and acute vitreous hemorrhage in either eye. For the purpose of submitting this measure, only unique occurrences with an onset of acute PVD and acute vitreous hemorrhage diagnosed within the current performance period will be denominator eligible, with the most recent occurrence (if there is more than one occurrence) being used for performance calculation.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed updating the measure submission frequency to once per performance period as simultaneous or very close-in-time bilateral PVDs are rare.[641] In the event the proposed substantive change(s) were finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to measure Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up. The commenter recommended CMS finalize the proposed changes to clarify the measure should be reported once per performance period. The commenter appreciated the assistance and input from CMS throughout the development of this measure. As indicated under Table D.28 of this Appendix, the commenters requested that CMS apply the 7-point scoring floor for this measure.

Response: We thank the commenters for supporting the substantive changes to this measure. There are policies in place that address when a 7-point score floor is applied, which does not include benchmark removal due to substantive changes. However, we will take the recommendation under advisement. While the measure data is not directly comparable, implementation of the measure in MIPS has been established and therefore does not meet the intent of the 'new measure' scoring policy, which is to incentivize adoption of new MIPS measures.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33160), we are finalizing the changes to measure Q501 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

[641] See footnote Retina Specialist, 2021.

D.30 Gains in Patient Activation Measure (PAM ®) Scores at 12 Months

	Description
CBE # / eCQM CBE #:	2483 / N/A
Quality #:	503
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The Patient Activation Measure® (PAM ®) is a 10- or 13-item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Substantive Change:	**Updated instructions: Removed:** Submission Criteria 4 and Performance Rate 3. **Updated denominator exclusion: Added: For all submission criteria:** Diagnosis of Delirium and Psychoactive substance abuse. **Updated denominator: Removed:** Submission Criteria 4. **Updated numerator: Removed:** Submission Criteria 4.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed removing Performance Rate 3 that measures the average change between baseline PAM® score and the percentage of patients 14 years and older who achieved a net increase of 6 points in a 4 to 12 month period as it is not technologically feasible to calculate using the existing submission JavaScript Object Notation (JSON) structure. As a result, the submission of data for the Submission Criteria 4 will not be required when reporting this measure. We also proposed excluding patients with a diagnosis of delirium and/or psychoactive substance abuse from the denominator of submission criteria 1, 2 and 3. This exclusion will ensure appropriate patients will be included in the denominator of the measure.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to measure Q503: Gains in Patient Activation Measure (PAM ®) Scores at 12 Months.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (90 FR 33161), we are finalizing the changes to measure Q503 as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

Table Group DD: Finalized Substantive Changes to Previously Finalized MIPS Quality Measures Available Only for Use in Relevant MVPs for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

As finalized for the CY 2024 performance period/2026 MIPS payment year and future years, the following three MIPS quality measures were retained for utilization in MVPs only while removed from traditional MIPS: Q112**:** Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128**:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79897 through 79902). We note that some MIPS quality measures available only in MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as finalized in the 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) is also specified as a collection type available for such measures described in Table Group DD.

Table Group DD within this final rule provides substantive changes finalized for the CY 2026 performance period/2028 MIPS payment year for MIPS quality measures available only in a relevant MVP. Two of the aforementioned MIPS quality measures, Q112 and Q113, had substantive changes proposed under Table Group DD. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2026 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2026 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2027. The 2026 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at https://qpp.cms.gov.

Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but it is important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2026 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

We requested comments on these substantive changes.

DD.1. Breast Cancer Screening

	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v14
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of women 40 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated description: For the eCQM collection type: Revised:** women 40-74 years of age. **Updated stratification: For the eCQM collection type: Added:** Report a total rate, and each of the following age strata: Stratum 1: Patients age 42-51 by the end of the measurement period Stratum 2: Patients age 52-74 by the end of the measurement period **Updated definition: For the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types: Added:** Reviewed – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the mammography report and discussed the findings with the patient. The mammography report may also be provided by the patient for the clinician's review / discussion during the visit and should be documented in the medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed making these changes to align with the latest clinical guidelines. We proposed adding a new rate to the measure to ensure continued benchmarking for the previously existing rate and to ensure continuous, undisrupted monitoring of performance across the specified age bands. Additionally, we proposed adding a definition for 'reviewed' to the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types to clarify the requirement for meeting the quality action. This will ensure the intent of measure was met and numerator compliance is consistently assessed across all submissions.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed substantive changes to measure Q112: Breast Cancer Screening. A few commenters specifically supported the expanded age range for the eCQM specification aligning with the MIPS CQM.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: Many commenters opposed the proposed changes to measure Q112 to the MIPS CQM and Medicare CQM collection types. Adding "reviewed" definition expands the measure's intent, increases documentation burden, and adds no value to patients or clinicians. Specifications should remain aligned across reporting options; eCQM does not include this requirement and it should not be added. The change would make it harder for ACOs to minimize data collection burden using EHRs. There is risk of overuse: repeat screenings may be ordered unnecessarily if prior documentation is not accessible. Physicians may feel compelled to discuss old results, causing confusion and unnecessary alarm. The commenters opposed any change to a measure that could encourage overuse of services, particularly a revision that is not directly tied to improving patient care. One of the commenters recommended CMS continue to allow "patient reported" results of the screening tests and add an additional "Performance Met" numerator option in order to allow for monitoring and appropriate segmentation of self-reported screenings.

Response: We disagree that by clarifying the definition of 'reviewed' as required to meet the numerator action expands the measure's intent, increases documentation burden, and adds no value to patients or clinicians. According to the American Cancer Society, breast cancer is the second most common cancer to afflict women in the U.S. and the second leading cause of cancer death in women.[642] The lapse of time between having a breast cancer screening performed and obtaining test results can be nerve-wracking and could potentially lead to worse health outcomes if cancer is present. There are a multitude of benefits for both the patient and provider in having a clinician review, discuss, and document the results/findings and discussion, including but not limited to, supporting shared decision-making[643] and ensuring continuity of care.[644] Although it is standard practice in healthcare to document care provided to a patient, including documenting a discussion upon the review of results/findings of a medical test or exam, the measure specification does not dictate the format or structure of such documentation. Clinicians may use their own discretion to decide how to document the review and discussion with their patients. Furthermore, there is no indication that reviewing, discussing, and documenting a patient's mammography results or report would encourage an overuse of services;

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[642] American Cancer Society. (2023). *Breast Cancer Facts & Figures 2023-2024.* American Cancer Society. https://www.cancer.org/research/cancer-facts-statistics/breast-cancer-facts-figures.html.
[643] Schrager, S. B., Phillips, G., & Burnside, E. (2017). A Simple Approach to Shared Decision Making in Cancer Screening. *Family Practice Management*, *24*(3), 5–10. https://pmc.ncbi.nlm.nih.gov/articles/PMC5697707/.
[644] National Comprehensive Cancer Network. (2025). *NCCN Guidelines for Patients®: Breast Cancer Screening and Diagnosis*. Version 2.2025. https://www.nccn.org/patients/guidelines/content/PDF/breastcancerscreening-patient.pdf.

however, studies have shown positive results such as shared decision-making and improved health outcomes.[645] However, we acknowledge the concerns raised and consider the most critical piece of this revision is ensuring clinician review of all reports. We also acknowledge that patient outreach for negative findings can add to clinician burden and potentially alarm patients. Therefore, we will not finalize the revision as proposed and will remove the requirement for patient discussion at this time.

Comment: A few commenters requested that CMS align the specifications of the Breast Cancer Screening and Colorectal Cancer Screening measures (Q112 and Q113) across measure types to ensure feasible reporting. A commenter stated the substantive change should be modified to include age group stratifications of 40-49 and 50-74 years of age to ensure proper alignment with current measure specifications and USPSTF recommendations.[646] Many commenters also recommended that CMS consider including patient refusal as an exception across the specifications for all reporting options in the future.

Response: We thank the commenters for their feedback. The age range for the eCQM collection type was different due to the earlier timeline for annual updates. To ensure the age is correctly analyzed, the stratification for the eCQM collection type measure reflects age 42 – 51 for stratum 1, which accounts for the 27-month lookback period. This allows for capturing patients from the age of 40 years. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q112 with modification for the CY 2026 performance period/2028 MIPS payment year and future years. We will remove the requirement for patient discussion from the definition of "reviewed" for the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types. The new definition will read: Reviewed – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the mammography report. The mammography report may also be provided by the patient for the clinician's review during the visit and should be documented in the medical record.

In addition to revising the requirements for "reviewed" for measure Q112, we will add the following clarifying language to the numerator note: While reviewing the results with the patient is not required for the purposes of reporting this measure, it is nonetheless best practice.

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[645] Schøllhammer, H., Jørgensen, T. M., & Jensen, H. I. (2023). Documenting Care Together with Patients: The Experiences of Nurses and Patients. *BMC Nursing*, *22*(1), 143. https://doi.org/10.1186/s12912-023-01309-6.
[646] U.S. Preventive Services Task Force. (2024). *Breast Cancer: Screening*. JAMA. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening.

DD.2. Colorectal Cancer Screening

	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v14
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated definition: For the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types: Added:** Reviewed – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the colorectal screening report and discussed the findings with the patient. The colorectal screening report may also be provided by the patient for the clinician's review / discussion during the visit and should be documented in the medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed adding a definition for 'reviewed' to the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types to clarify the requirement for meeting the quality action. This will ensure the intent of measure was met and numerator compliance is consistently assessed across all submissions.

We note that under the substantive changes row that references to "mammography" in the proposed rule (90 FR 33162) were corrected to "colonoscopy" in the Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Correction (90 FR 39160). We further update the terminology in this final rule to "colorectal screening" to align with the measure specifications.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed substantive changes to measure Q113: Colorectal Cancer Screening.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: A commenter supported requiring clinicians to review colorectal cancer screening results and discuss findings with patients but raised concerns that the proposed language to measure Q113 only applied to colonoscopy reports. The commenter urged CMS to revise the requirement to include all colorectal cancer screening methods, noting that Medicare covers multiple options, including non-invasive tests that are critical for expanding access. They emphasized that abnormal non-invasive test results require a follow-up colonoscopy to complete screening, and evidence shows patients who do not receive this follow-up face twice the risk of death from colorectal cancer. The commenter stressed that poor communication of abnormal results is a major reason patients fail to complete needed colonoscopies.

Response: We thank the commenter for supporting the substantive changes to this measure and encourage them to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: Same as their comments on table DD.1 of this Appendix, a few commenters did not support the proposed substantive changes to measure Q113 for the MIPS CQM and Medicare CQM collection types, specifically the addition of a definition for "reviewed" to qualify as meeting the quality action. The commenters believed this change is an expansion beyond the original intent of the measure and adds unnecessary documentation burden for clinicians without delivering meaningful improvements in patient care or outcomes. The commenters believed this change could lead to a negative unintended consequence of overuse of this procedure. The commenters opposed any change to a measure that could encourage overuse of services, particularly a revision that is not directly tied to improving patient care. One of the commenters recommended CMS continue to allow "patient reported" results of the screening tests and add an additional "Performance Met" numerator option in order to allow for monitoring and appropriate segmentation of self-reported screenings. A commenter requested that CMS work with NCQA to ensure that the colorectal cancer quality measures utilized across CMS programs incorporate all FDA-authorized, Medicare-covered screening tests.

Response: We disagree that by clarifying the definition of 'reviewed' as required to meet the numerator action expands the measure's intent, increases documentation burden and adds no value to patients or clinicians. Colorectal cancer is the third-leading cause of cancer-related deaths in men and the fourth leading cause in women, but it's the second most common cause of cancer deaths when numbers for men and women are combined in the United States.[647] The lapse of time between having cancer screening performed and obtaining test results can be nerve-wracking. There are a multitude of benefits for both the patient and provider in having a clinician review, discuss, and document the results/findings and discussion, including but not limited to,

[647] American Cancer Society. (2025). *Key Statistics for Colorectal Cancer*. https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html.

supporting shared decision-making[648] and ensuring continuity of care.[649] Although it is standard practice in healthcare to document care provided to a patient, including documenting a discussion upon the review of results/findings of a medical test or exam, the measure specification does not dictate the format or structure of such documentation. Clinicians may use their own discretion to decide how to document the review and discussion with their patients. Furthermore, there is no indication that reviewing, discussing, and documenting a patient's mammography results or report would encourage an overuse of services; however, studies have shown positive results such as shared decision-making and improved health outcomes.[650] However, we acknowledge the concerns raised and consider the most critical piece of this revision is ensuring clinician review of all reports. Therefore, we will not finalize the revision as proposed and will remove the requirement for patient discussion at this time.

After consideration of public comments, we are finalizing the changes to measure Q113 with modification for the CY 2026 performance period/2028 MIPS payment year and future years. We acknowledge that patient outreach for negative findings can add to clinician burden and clinicians should focus their time on improving communication around abnormal findings; therefore, we will remove the requirement for patient discussion from the definition of "reviewed" for the MIPS CQM, Medicare Part B Claims Measure, and Medicare CQM collection types. The new definition will read: Reviewed – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the colorectal screening report. The colorectal screening report may also be provided by the patient for the clinician's review during the visit and should be documented in the medical record.

In addition to revising the requirements for "reviewed" for measure Q113, we will add the following clarifying language to the numerator note: While reviewing the results with the patient is not required for the purposes of reporting this measure, it is nonetheless best practice.

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[648] See footnote Schrager et al., 2017.
[649] National Cancer Institute. (2025). *Communication in Cancer Care (PDQ®)–Health Professional Version*. https://www.cancer.gov/about-cancer/coping/adjusting-to-cancer/communication-hp-pdq#_174.
[650] See footnote Schøllhammer et al., 2023.

APPENDIX 2: IMPROVEMENT ACTIVITIES

In the CY 2026 PFS proposed rule (90 FR 32724), we proposed, beginning with the CY 2026 performance period/2028 MIPS payment year, to add three new improvement activities (as specified in Table F-B1), modify seven previously finalized improvement activities (as specified in Table F-B2), and remove eight previously finalized improvement activities (as specified in Table F-B3). We are also proposed to add a new activity subcategory and remove a subcategory. These proposals are discussed in section IV.A.4.d of this final rule and in more detail below. We solicited comments on our proposals.

Except as otherwise noted in this final rule, previously finalized improvement activities will continue to apply for the CY 2026 performance period/2028 MIPS payment year and future years.

TABLE F-B1: New Improvement Activities
Adoption Beginning with the CY 2026 Performance Period/2028 MIPS Payment Year

New Improvement Activity	
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Improving Detection of Cognitive Impairment in Primary Care
Activity Description:	To increase the detection rate of cognitive impairment, particularly in early stages, the MIPS eligible primary care clinician must perform the following activities: ● Determine his/her baseline detection rates for mild cognitive impairment (MCI), dementia, and cognitive impairment at either stage using the tool provided for this Improvement Activity ● If any of the three rates are below 1.0: ++Increase the uptake of the Annual Wellness Visit ++Ensure that each Annual Wellness Visit contains a structured cognitive assessment ++Include a question about subjective memory concerns to the collection of vital signs during intake for patients 65+, and conduct a structured cognitive assessment in those with concerns ● Remeasure detection rates for MCI, dementia, and cognitive impairment at either stage quarterly This Improvement Activity should only focus on Medicare patients aged 65 and older, given the strong correlation of cognitive impairment with age.
Rationale:	Recent publications of phase three trial results reported that two amyloid-targeting drugs were able to significantly reduce the speed of cognitive decline in patients with early-stage Alzheimer's disease, the most common cause of dementia. One drug, lecanemab, is now FDA-approved for treatment of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease, and the other drug, donanemab, is awaiting the FDA's decision. These drugs are only indicated in early disease stages, lending renewed urgency to the problem of delayed and missed diagnosis of cognitive decline while, today, cognitive decline is usually detected in advanced stages.[1,2] For example, Thoits et al. found that about 79 percent of randomly selected patients, who were newly diagnosed at a memory clinic, had moderate or severe dementia.[3] Such delayed diagnoses have long taken away from patients and families the opportunity to adopt lifestyle changes to reduce the speed of decline,[4] start symptomatic medication treatment, and consider measures to increase physical and financial safety and security.[5] But now failing to detect early-stage Alzheimer's disease will deprive patients of the prospect to alter the course of this devastating illness. Unfortunately, limited data exist for the degree of missed diagnoses of MCI, the stage at which Alzheimer's disease would ideally be treated.[6] White et al. used data from the Health and Retirement Study (HRS) to determine that 11.4 percent of subjects with incident MCI reported receiving a timely diagnosis,[7] and Savva et al. analyzed neuropsychiatric testing data from the Aging, Demographics and Memory Study ADAMS data to conclude that 15 percent of participants with a Clinical Dementia Rating of 0.5, a score reflective of MCI, were aware of a diagnosis of cognitive impairment.[8] Only nine percent of expected MCI cases are diagnosed in the U.S. Medicare population.[9]

	More research has been conducted on dementia detection rates. One study linked Medicare claims data to information on 417 patients with a clinical diagnosis of Alzheimer's disease in the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) data and reported that only around 75 percent of patients had a corresponding diagnosis in claims data in the period from 1991 to 1999,[10] a number similar to the 85 percent reported by Lee et al. for the 2007 to 2012 period of the same data.[11] Zhu et al. published a dementia prevalence of 12.9 percent based on cognitive tests and of 12.4 percent based on diagnosis codes in the 20 percent Medicare sample in 2012.[12] Jutkowitz et al. found considerably lower dementia diagnosis rates of 5.6 percent and 6.5 percent in 2014 and 2016, respectively, in a convenience sample of three Medicare Advantage Plans.[13] Our own data suggest a slightly higher rate of dementia diagnoses than expected, although some of that could be miscoding of MCI as dementia, and the overall detection rate of cognitive impairment remains far lower than expected, especially for minority and low SES patients.[14] In summary, there is substantial evidence that cognitive impairment remains underdiagnosed, particularly in early stages. Measuring diagnosis rates in primary care and comparing those to expected rates given the demographic composition of a clinician's panel can identify gaps in diagnosis and point primary care clinicians towards efforts to proactively inquire about cognitive concerns and follow up on subjective memory complaints, particularly in high-risk and disadvantaged populations. The Medicare Annual Wellness Visit provides an opportunity to do so, but this benefit remains underutilized. A 2020 study found that only one-half of beneficiaries took advantage of it, and fewer than one-third reported having a structured cognitive assessment.[15] A recent expert group recommended several steps to routinely incorporate brief cognitive assessment into primary care workflows.[16] Thus, steps can be taken at both the individual clinician and the organizational level to detect cognitive impairment more frequently and earlier so that patients can potentially benefit from disease-modifying treatments.
New Improvement Activity	
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Integrating Oral Health Care in Primary Care
Activity Description:	MIPS eligible clinicians that practice primary care will include an oral health risk assessment and intraoral screening as part of a patient's primary care management. The MIPS eligible clinician will provide education and counseling to the patient to include the importance of oral health and the impact of oral health on systemic diseases. For patients without a dental home and/or those with oral health needs, a dental referral will be provided. To receive credit for this activity, a MIPS eligible clinician must complete two Smiles for Life (https://www.smilesforlifeoralhealth.org) trainings: ("The Oral Examination" and "Geriatric Oral Health"). These are one-time, free, online training 60-minute certification courses. Smiles for Life oral health education has been adopted by Medicaid in several states to improve oral health access, outcomes, and referrals for children through educating medical providers. The MIPS eligible clinician must include one or more of the following activities in addition to completing the training: o Create a dental referral network list by specialty and accepted insurances. o Include applicable oral health screening questions in the patient health intake forms (dentist of record, date of the last dental exam, and personal oral hygiene routine). o Identify an applicable caries risk assessment tool to be used. o Include intraoral health screening and referral to dental provider as part of a patient's primary care management. o Provide education and counseling to patients about the importance of oral health and impact on systemic disease.

	o Refer patients without a dental home and/or those who have untreated dental disease indicated by health history, caries risk assessment, Intraoral health screening, medications and/or concerns reported by patient. o Include a description of the findings found in all dental referrals. ++ Documents with appropriate procedure and diagnostic codes to track services provided and referrals to validate performance of the improvement activity.
Rationale:	Oral health is closely related to overall health. According to the Centers for Disease Control and Prevention (CDC), approximately 35 percent of American adults did not see a dentist in the past year.[17] The Kaiser Family Foundation (KFF) identified nearly half of all people on Medicare have no dental coverage, and the CDC identified one out of six adults 65 or older are completely edentulous (have lost all their teeth), which can greatly impact nutrition.[18,19] Moreover, a significant portion of the Medicare population has or is at risk for chronic health conditions, which can be further complicated by poor oral health. Dental issues can be early indicators of systematic diseases, such as Alzheimer's, and may also lead to severe health complications such as diabetes and cardiovascular disease, all of which have a significant impact on the Medicare population. For example, researchers have concluded that periodontal disease "might be a modifiable risk factor" for Alzheimer's disease. Moreover, Medicare spends $520 million annually on dental-related emergency department. If these issues were caught and managed early, many of those expenditures could be avoided. With nearly two-thirds of the older adult population in the United States experiencing periodontitis, the WHO has suggested that integrating age-appropriate oral health concerns into general medicine may lead to improvements in older adults' oral health conditions and improve quality of life.[20] As patients visit their primary care office for medical treatment, there is an opportunity for primary care providers to address oral health by assessing oral health risk and reinforcing at-home care messaging, creating an access point for patients who might not otherwise seek dental care. By including quick oral evaluations during routine medical exams, medical providers can ensure comprehensive patient care and early interventions for potential health issues. There is growing evidence that health outcomes improve when dental assessments by medical professionals are integrated into care.[21]This medical-dental integration (MDI) activity can positively address the oral health needs of a high-risk and medically complex population by increasing access, and promoting comprehensive, continuous patient care. Oral health assessment activities do not require extensive time, training, or resources to complete. An oral health assessment can be done in five minutes. Training through the Smiles for Life curriculum offers a course on oral health assessments (titled: "The Oral Examination") and is a one-time, free, online certification. Smiles for Life oral health education has been adopted by Medicaid programs in several states to improve oral health access, outcomes, and referrals for children through educating medical providers. Billable and diagnostic codes exist along with an American Dental Association CAMBRA risk assessment form readily available for adoption. Reporting is minimal and involves documentation of the codes indicated below and pulling a report on those codes from the EHR. Additional research about HEENT (head, eyes, ears, nose, and throat) assessment expanded to HEENOT (head, ears, eyes, nose, oral, and throat) through integration of an interprofessional educational (IPE) activity developed for University of Colorado NP and dental students has been published.[22] Creating a referral network of dental providers and completing referrals to these providers will ensure that oral health assessments result in patients getting the additional care they need. To complete this activity, medical providers will be required to implement a process, contact local providers, and assess their capacity.
New Improvement Activity	
Activity ID:	IA_PSPA_XX
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Patient Safety in Use of Artificial Intelligence (AI)

Activity Description:	Develop a new data-collection field within patient safety reporting systems for AI-attributable events, which would include both actual harm as well as near misses. When an event is identified, a process to identify the cause and plan for future mitigation is documented. AI-attributable events are defined broadly to include not only automated or semi-automated devices, but any electronic tool that is being used to support clinical decision making.
Rationale:	AI is transforming healthcare and carries with it the promise of faster and potentially more accurate diagnoses and improved health outcomes, but also potential issues that could put individuals' safety at risk. Misdiagnosis and/or failure to properly treat illness as a result of AI errors may jeopardize the health and safety of patients. With broadly collected data on adverse patient outcomes (and near-misses) attributable to AI, MIPS eligible clinicians will be better equipped to identify patterns that can inform decisions to modify use of specific AI tools to optimize care for individual patient populations. This proposed new activity—with a focus on both data-collection and processes to identify causes of adverse events and near-misses to plan for future safety improvement—has a high potential to improve patient care. Defining AI-attributable events broadly to include not only automated or semi-automated devices, but any electronic tool that is being used to support clinical decision making, will likely lead to widely applicable improvements in patient safety, both in patients' experience of care and outcomes. We received public comments on the new improvement activities proposals. The following is a summary of the comments we received and our responses. *Comment*: We received several public comments in support of the proposed new activities. We also received comments regarding how to make the proposed new AI activity as robust as possible. *Response*: We appreciate the public's support of these proposed new activities. We will take this input into account, particularly when drafting the subregulatory guidance for the proposed new AI activity. After consideration of public comments, we are finalizing these new improvement activities as proposed.

[1] Van Dyck, C. H., Li, Q., Evans, M., & et al. (2022). *Lecanemab in early Alzheimer's disease: A phase 3, randomized, double-blind, placebo-controlled trial*. *Lancet, 399*(10329), 881-890. https://doi.org/10.1016/S0140-6736(22)00035-2.

[2] Sims, J. R., Cummings, J., Burns, A., & et al. (2023). *Efficacy of donanemab in early Alzheimer's disease: Results of a phase 3 trial*. *JAMA Neurology, 80*(1), 12-22. https://doi.org/10.1001/jamaneurol.2022.4631.

[3] Thoits, P. A., et al. (2018). Dementia severity by living situation. *ResearchGate*. Retrieved from https://www.researchgate.net/figure/Dementia-Severity-by-Living-Situationa_tbl2_323172939ResearchGate.

[4] Ngandu, T., Lehtisalo, J., Solomon, A., et al. (2015). A 2-year multidomain intervention of diet, exercise, cognitive training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people (FINGER): a randomised controlled trial. *The Lancet, 385*(9984), 2255-2263. https://doi.org/10.1016/S0140-6736(15)60461-5ScienceDirect+3The Lancet+3PubMed+3.

[5] Dubois, B., Epelbaum, S., Nyasse, F., Bakardjian, H., Gagliardi, G., Uspenskaya, O., et al. (2018). Cognitive and neuroimaging features and brain β-amyloidosis in individuals at risk of Alzheimer's disease (INSIGHT-preAD): a longitudinal observational study. *Lancet Neurology, 17*(4), 335–346. https://doi.org/10.1016/S1474-4422(18)30029-2PMC.

[6] Cummings, J., Lee, G., & Zhong, K. (2023). Alzheimer's disease drug development pipeline: 2023. *Alzheimer's & Dementia: Translational Research & Clinical Interventions, 9*(1), e12385. https://doi.org/10.1002/trc2.12385.

[7] White, L., Ingraham, B., Larson, E., Fishman, P., Park, S., & Coe, N. B. (2021). Observational study of patient characteristics associated with a timely diagnosis of dementia and mild cognitive impairment without dementia. *Journal of General Internal Medicine, 37*(12), 2957–2965. https://doi.org/10.1007/s11606-021-07169-7.

[8] Savva, G. M., & Arthur, A. (2015). Who has undiagnosed dementia? A cross-sectional analysis of participants of the Aging, Demographics and Memory Study. *Age and Ageing, 44*(4), 642–647. https://doi.org/10.1093/ageing/afv020.

[9] Mattke, S., Jun, H., Chen, E., Liu, Y., Becker, A., & Wallick, C. (2023). Expected and diagnosed rates of mild cognitive impairment and dementia in the U.S. Medicare population: Observational analysis. *Alzheimer's Research & Therapy, 15*(1), 128. https://doi.org/10.1186/s13195-023-01272-z.

[10] Taylor, D. H. Jr., Sloan, F. A., & Doraiswamy, P. M. (2004). Marked increase in Alzheimer's disease identified in Medicare claims records between 1991 and 1999. *The Journals of Gerontology: Series A, 59*(7), M762–M766. https://doi.org/10.1093/gerona/59.7.m762.

[11] Lee, E., Gatz, M., Tseng, C., Schneider, L. S., Pawluczyk, S., Wu, A. H., & Deapen, D. (2019). Evaluation of Medicare claims data as a tool to identify dementia. *Journal of Alzheimer's Disease, 67*(2), 769–778. https://doi.org/10.3233/JAD-181005.

[12] Haye, S., Thunell, J., Joyce, G., Ferido, P., Tysinger, B., Jacobson, M., & Zissimopoulos, J. (2023). *Estimating the potential budgetary impact of lecanemab in the United States*. *Alzheimer's & Dementia: Diagnosis, Assessment & Disease Monitoring, 15*(1), e12472. https://doi.org/10.1002/dad2.12472.

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In the CY 2026 PFS proposed rule (90 FR 32724 through 32725), we proposed modifications to **seven** previously finalized improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year as specified in Table F-B2.

Specifically, we proposed to reassign **five** previously finalized improvement activities currently specified for the Achieving Health Equity subcategory to other subcategories that better fit their intended purpose. We also proposed to reassign **one** previously finalized improvement activity to the proposed new subcategory Advancing Health and Wellness. Finally, we proposed several modifications to **one** previously finalized improvement activity, IA_BMH_1.

We refer readers to our discussion in section IV.A.4.d.(3)(b)(vii) of this final rule and in more detail below.

TABLE F-B2: Changes to Previously Finalized Improvement Activities for the CY 2026 Performance Period/2028 MIPS Payment Year and for Future Years

Current Improvement Activity	
Current Activity ID:	**IA_BMH_1**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Diabetes screening
Current Activity Description:	Diabetes screening for people with schizophrenia or bipolar disease who are using antipsychotic medication.
Change and rationale:	We proposed to modify this activity to broaden the relevant patient population by requiring a comprehensive physical health screening on all patients taking anti-psychotic medications. This proposed modification would encompass a broader range of health conditions that may be impacted by antipsychotic medications, beyond just diabetes. To better reflect the substantive modifications we proposed for this activity, we also proposed to modify this activity's current title, "Diabetes screening," to change it to "Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring." Antipsychotic medications are an important tool for treating a wide range of mental health disorders including schizophrenia, bipolar disease, major depressive disorder, post-traumatic stress disorder, and for agitation associated with dementia due to Alzheimer's disease. In the U.S., approximately 3.8 million citizens reported taking antipsychotics in a 2013-2018 National Health and Nutrition Examination Survey (NHANES).[1] Antipsychotic use is increasing – the Agency for Healthcare Research and Quality (AHRQ) found that 6.1 million people obtained at least one prescription for antipsychotics in 2018, a 22.3 percent increase from 2013.[2] A large percentage of this growth may be due to the substantial increase in the use of these medications for off - label conditions. Inappropriate use of antipsychotics in nursing homes and long-term care facilities is a public health concern. CMS' National Partnership to Improve Dementia Care in Nursing Homes recent antipsychotic medication use data report indicates 14.5 percent of residents who are not diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome were prescribed antipsychotics in 2021 Q4.[3] These patients should also be considered for routine monitoring and assessment for antipsychotic-associated physical health conditions. Antipsychotic medications are effective in managing symptoms of psychiatric conditions; however, adverse health effects such as obesity, diabetes, metabolic syndrome, cardiovascular disease, and medication-induced movement disorders such as tardive dyskinesia (TD) may be induced or exacerbated by their use. Physical health conditions associated with antipsychotic medications may substantially impact healthcare system costs, and effective assessment and monitoring is important for achieving improved beneficiary health outcomes. Metabolic adverse conditions can

	significantly influence risk for morbidity and mortality with long-term use. TD diagnoses diminish physical wellness and social functioning, and adversely affect patients' health-related quality of life.[4] Cost analysis of treatment by the U.S. Department of Veterans Affairs (VA) for patients with schizophrenia who developed diabetes showed an average marginal cost of $3,100. An evaluation of children and adolescents treated with antipsychotic medications through Medicaid showed that patients who experienced cardiometabolic adverse events incurred 34 percent higher total care costs over time. A Medicaid claims analysis for adults with schizophrenia found mean total care costs for patients with incident cardiometabolic conditions were about $1,249 higher than costs incurred by those without these conditions.[5] A retrospective analysis demonstrated that patients with TD had more inpatient admissions (55.5 percent vs. 26.1 percent), emergency room visits (61.5 percent vs. 50.6 percent), and total healthcare costs ($54,656 vs. $28,777) than patients treated for schizophrenia, bipolar disorder, major depressive disorder, or other psychiatric disorders without a diagnosis of TD.[6] The American Psychiatric Association, American Diabetes Association, American Association of Clinical Endocrinologists, and North American Association for the Study of Obesity have developed clinical guidelines recommending laboratory tests and physical examinations for initial evaluations and subsequent monitoring during treatment.[7,8,9] Routine components of antipsychotic assessment and monitoring include: + Personal and family history of obesity, diabetes, dyslipidemia, hypertension, or cardiovascular disease; +Body Mass Index (BMI); +Waist circumference; +Blood pressure; +Fasting plasma glucose; +Fasting lipid profile; and +Clinical assessment of abnormal movements, such as through the Abnormal Involuntary Movement Scale (AIMS). While clinical examination and testing for physical health conditions associated with antipsychotic medications are recommended for baseline assessment and routine monitoring is critical to reduce morbidity, mortality, and costs associated with these conditions, evidence demonstrates clinical gaps in care: • In a quality improvement study, a random sample of 30 patient records of adult patients on antipsychotic medications from a psychiatry outpatient clinic between October 2016 and September 2017 found only one patient had documentation of an AIMS examination.[10] • In a quality improvement study, analysis found only one (2.9 percent) study subject met standards for compliance with TD assessments.[11] • A retrospective study of patients prescribed second generation antipsychotics in a Federally Qualified Health Center found baseline glucose and lipid monitoring rates of 50 percent and 23 percent, respectively; three month monitoring rates of 37 percent and 26 percent, respectively; and annual rates of 71 percent and 40 percent, respectively.[12] • A survey-based study found metabolic monitoring rates for patients prescribed atypical antipsychotic medications was nine percent for youth in their first year of medication use and 58.9 percent in subsequent years on medication.[13] • A study of 32 Veterans Affairs facilities found low rates of metabolic monitoring at baseline and follow up (67 percent versus 49 percent for weight, 46 percent versus 27 percent for glucose or hemoglobin A1c, and 32 percent versus 16 percent for LDL.[14] • A retrospective cohort including over 23,000 patients on second-generation antipsychotics reported baseline lipid testing rates of 10.5 percent and glucose testing rates of 21.8 percent after the 2004 ADA consensus statement was issued.[15] • Studies have shown less than 20 percent of patients receiving baseline glucose testing and less than 10 percent receiving baseline lipid testing.[16]Several quality improvement studies have demonstrated real-world implementation of interventions that go beyond common clinical practice. Specifically, evidence from these studies demonstrates that the implementation of quality improvement interventions described in this improvement

activity have contributed to improvements in beneficiary care and health outcomes:
• Quality improvement projects focused on the use of collaborative practice agreements or enhanced movement disorder screening services increased AIMS screening.[17] In addition, projects focused on improving metabolic monitoring through collaborative agreements improved compliance with monitoring[18] and improved HbA1c.[19] Studies have also demonstrated pharmacist-physician collaborative care models for other clinical areas, such as hypertension, have resulted in lower downstream medical expenditures compared to standard of care.[20]
•
• Implementation of EHR-integrated alerts demonstrated increased rates of cardiometabolic monitoring and documentation.[21,22]
• Standardized data collection protocols increased cardiometabolic monitoring [23], and AIMS screening rates.[24]

This improvement activity can be linked to existing and related MIPS measures across Performance Categories:
• MIPS Quality measures:
o Q001 Diabetes: HbA1c Poor Control (>9%)
o Q317 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented
o Q383 Adherence to Antipsychotic Medications for Individuals with Schizophrenia
o Q502 Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder
• MIPS Cost measures:
o Psychoses and Related Conditions
o Movement Disorders (currently under development)
• MIPS Value Pathways
o Quality Care in Mental Health
o Substance Use Disorders

Regarding CMS' optional Improvement Activity acceptance criteria, as listed in the CY 2024 Call for Improvement Activities (*https://qpp.cms.gov/resources/document/e18576b5*),[25] this Improvement Activity aligns in multiple areas.
Support for the patient's family or personal caregiver: This Improvement Activity supports patients' families and caregivers. Caregivers for patients with schizophrenia have noted significant strains[26] and the need to fulfill a mediator role between the patient and the provider; improved assessment and monitoring could contribute to reductions in stress pertaining to the impact of physical health conditions associated with antipsychotic medications and burden of obesity, diabetes, and movement disorders.
Responds to a Public Health Emergency as determined by the Secretary: While this Improvement Activity does not respond to a current public health emergency, we believe improving assessment and monitoring of physical health conditions associated with antipsychotic medications aligns with Centers for Medicare & Medicaid Services strategies to mitigate impacts of inappropriate antipsychotic use in nursing home settings and among patients with dementia. Patients exposed to long-term use of inappropriate antipsychotics are at risk for cardiometabolic conditions and movement disorders and improved assessment and monitoring can mitigate the impact of these conditions on beneficiaries' overall health.[27]
Addresses improvements in practice to reduce health care disparities: This Improvement Activity focuses on areas of healthcare inequity, and its implementation can support reduction of health disparities. African Americans are more often prescribed older medications that increase risk for TD and extrapyramidal physical health conditions.[28,29] Further, Medicaid members are disproportionately impacted by TD, and nearly one in eight Medicaid members receiving antipsychotics developed TD within a year of treatment.[30]

Focus on meaningful actions from the person and family's point of view: Improving assessments and monitoring for antipsychotic medication use is a meaningful person- and family-centered activity. Medication-induced movement disorders such as TD have a significant impact on patient wellbeing. Studies have demonstrated that 50 percent to

	60 percent of TD patients believed self-conscious or embarrassed by their condition, with moderate to severe movements being intolerable, painful, physically disabling, and in some scenarios eventuating in depression and suicide. TD is further associated with poorer quality of life, stigma, increased mortality, and medication non-adherence.[31,32] *Representative of activities that multiple individual MIPS eligible clinicians or groups could perform:* This Improvement Activity is relevant to and can be performed by a variety of MIPS eligible clinician specialty types, including: • Primary care physicians, including nurse practitioners, medical assistants, and physician assistants treating patients prescribed antipsychotic medications • Psychiatrists and advanced practice providers (for example, nurse practitioners, medical assistants, and physician assistants) treating patients with a wide range of mental health conditions from schizophrenia, to depression, to PTSD and more, who are prescribed antipsychotic medications • Neurologists and advanced practice providers (for example, nurse practitioners, medical assistants, and physician assistants) responsible for monitoring patients on antipsychotic medications who are at-risk for medication-induced movement disorders.
Revised Activity Title:	Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring
Revised Activity Description:	MIPS eligible clinicians must implement at least one process improvement during treatment of patients taking anti-psychotic medication related to one or more component(s) of appropriate antipsychotic medication assessment and monitoring. Components include: • Personal and family history of obesity, diabetes, dyslipidemia, hypertension, or cardiovascular disease; • Body Mass Index (BMI); • Waist circumference; • Blood pressure; • Fasting plasma glucose; • Fasting lipid profile; • Clinical assessment of abnormal movements, such as through the Abnormal Involuntary Movement Scale (AIMS). Process improvements must include at least one of the following types of activities: • Establishing and disseminating educational materials (for example, online or in-person training sessions) to educate clinical teams about physical health monitoring and protocols for monitoring (for example, AIMS assessment for medication-induced movement disorders); • Creating and implementing monitoring templates and protocols (for example, EHR-integrated flags), to standardize collection and documentation of one or more components of physical health monitoring; or • Establishing collaborative service agreements with an enhanced monitoring service, (for example, pharmacist-led monitoring clinic) to monitor for antipsychotic associated physical health condition and either adjust medications (for example, diabetes medications) based on laboratory results or refer patients for further assessments (for example, AIMS).”

In the CY 2026 PFS proposed rule (90 FR 32724), we proposed modifying the following improvement activities by reassigning in which subcategory they are beginning with the CY 2026 performance period/2028 MIPS payment year.

We proposed to reassign the following five improvement activities to new subcategories: IA_AHE_1, Enhance Engagement of Medicaid and Other Underserved Populations; IA_AHE_3, Promote use of Patient-Reported Outcome Tools; IA_AHE_6, Provide Education Opportunities for New Clinicians; IA_AHE_7, Comprehensive Eye Exams; and IA_AHE_10, Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data.

Specifically, we proposed to reassign: IA_AHE_1 and IA_AHE_6 to the Expanded Practice Access subcategory, thereby more specifically highlighting these activities’ aim to increase access to health care services and providers; IA_AHE_3 and IA_AHE_7 to the Beneficiary Engagement subcategory, thus focusing more on these activities’ action to increase beneficiary engagement; and IA_AHE_10 to the Patient Safety and Practice Assessment subcategory, since this activity particularly relates to patient safety improvement.

We also proposed to reassign the IA_PM_13, Chronic Care and Preventative Care Management for Empaneled Patients, to the proposed new subcategory, Advancing Health and Wellness, better reflecting this activity's primary focus on population health and wellness.

These activities are being proposed for reassignment to designated subcategories based on the description and rationale for each as well as based on which subcategory best fits the individual activity's purpose.
We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments expressing support for reassigning these existing activities as proposed. Additionally, we received several public comments in support of the modification to IA_BMH_1; we also received some suggestions regarding how to make this proposed modification as robust as possible.

Response: We appreciate the supportive comments. For the modification of IA_BMH_1 we will take into consideration the suggestions for making the modifications robust. We appreciate the public's support of our proposed activity modifications /reassignments. We will take the public's input into account, particularly when drafting the validation criteria for these proposed reassigned activities, as well as in future rulemaking.

Comment: Most commenters opposed the removal of the Achieving Health Equity subcategory, expressing concern that its elimination would diminish efforts to address disparities in healthcare access, quality, affordability, and outcomes. Some commenters believe the replacement of the Achieving Health Equity subcategory with a wellness-based subcategory is too limited in scope to meaningfully address health disparities, whereas the Achieving Health Equity directly targets systemic inequities and social determinants of health through focused, equity-driven improvement activities. Many commenters expressed support for the addition of the Advancing Health and Wellness subcategory. However, a commenter also recommended that we clearly define and establish how "well-being" will be measured before it is adopted as a formal requirement. Additionally, commenters recommended developing improvement activities that still focus on upstream drivers of health.

Response: The removal of the Achieving Health Equity subcategory does not lessen the focus on improving access to care, enhancing patient well-being, or supporting preventative measures that influence health outcomes. Instead, replacing it with a wellness-based subcategory broadens the perspective to emphasize prevention, holistic care, mental and behavioral health, and lifestyle approaches that promote well-being for all individuals. This expanded framing encourages a more inclusive and proactive approach that supports better health across diverse populations. By highlighting wellness and comprehensive care, the new structure helps clinicians and organizations focus on practical strategies that strengthen overall patient outcomes and community health.

After consideration of public comments, we are finalizing these activity modifications as proposed.

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In the CY 2026 PFS proposed rule (90 FR 32725), we proposed to remove **eight** previously finalized improvement activities beginning with the CY 2026 performance period/2028 MIPS payment year. These changes are discussed in section IV.A.4.d.(3)(b)(viii) of this final rule and in more detail below. Specifically, we proposed to remove each of these eight improvement activities in accordance with the policy at § 414.1355(d), specifically under Factor 7 (Activity is obsolete) (§ 414.1355(d)(7).

TABLE F-B3: Improvement Activities Being Removed for the CY 2026 Performance Period/2028 MIPS Payment Year and for Future Years

Current Improvement Activity	
Current Activity ID:	**IA_ AHE_5**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
Current Activity Description:	Lead clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes. Research could include addressing health-related social needs like food insecurity, housing insecurity, transportation barriers, utility needs, and interpersonal safety.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_8**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Create and Implement an Anti-Racism Plan
Current Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools. The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	

Current Activity ID:	**IA_AHE_9**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
Current Activity Description:	Create or improve, and then implement, protocols for identifying and providing appropriate support to: (a) patients with or at risk for food insecurity, and (b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.) Actions to implement this improvement activity may include, but are not limited to, the following: ● Use Malnutrition Quality Improvement Initiative (MQii) or other quality improvement resources and standardized screening tools to assess and improve current food insecurity and nutritional screening and care practices. ● Update and use clinical decision support tools within the MIPS eligible clinician's electronic medical record to align with the new food insecurity and nutrition risk protocols. ● Update and apply requirements for staff training on food security and nutrition. ● Update and provide resources and referral lists, and/or engage with community partners to facilitate referrals for patients who are identified as at risk for food insecurity or poor nutritional status during screening. Activities must be focused on patients at greatest risk for food insecurity and/or malnutrition—for example patients with low income who live in areas with limited access to affordable fresh food, or who are isolated or have limited mobility.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_11**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients
Current Activity Description:	Create and implement a plan to improve care for lesbian, gay, bisexual, transgender, and queer (LGBTQ+) patients by understanding and addressing health disparities for this population. The plan may include an analysis of sexual orientation and gender identity (SO/GI) data to identify disparities in care for LGBTQ+ patients. Actions to implement this activity may also include identifying focused goals for addressing disparities in care, collecting and using patients' pronouns and chosen names, training clinicians and staff on SO/GI terminology (including as supported by certified health IT and the Office of the National Coordinator for Health Information Technology US Core Data for Interoperability [USCDI]), identifying risk factors or behaviors specific to LGBTQ+ individuals, communicating SO/GI data security and privacy practices with patients, and/or utilizing anatomical inventories when documenting patient health histories.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. CMS is evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_12**

Current Subcategory:	Achieving Health Equity
Current Activity Title:	Practice Improvements that Engage Community Resources to Address Drivers of Health
Current Activity Description:	Select and screen for drivers of health that are relevant for the eligible clinician's population using evidence-based tools. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded questions/fields for the capture of data. After screening, address identified drivers of health through at least one of the following: ● Develop and maintain formal relationships with community-based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or ● Work with community partners to provide and/or update a community resource guide for to patients who are found to have and/or be at risk in one or more areas of drivers of health; or ● Record findings of screening and follow up within the electronic health record (EHR); identify screened patients with one or more needs associated with drivers of health and implement approaches to better serve their holistic needs through meaningful linkages to community resources. Drivers of health (also referred to as social determinants of health [SDOH] or health-related social needs [HSRN]) prioritized by the practice might include, but are not limited to, the following: food security; housing stability; transportation accessibility; interpersonal safety; legal challenges; and environmental exposures.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_PM_26**
Current Subcategory:	Population Management
Current Activity Title:	Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B
Current Activity Description:	Demonstrate that the MIPS eligible clinician's practice has achieved and/or maintained a vaccination rate of 60 percent of clinical practice staff for COVID-19, and 80 percent for influenza. Demonstrate vaccination, immunity, or non-responder status to hepatitis B for 95 percent of clinical practice staff. Vaccination recommendations are from Centers for Disease Control and Prevention; staff with contraindications to the vaccinations, as determined by the CDC, are excluded from the requirements. Vaccines and Immunizations | CDC.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being. Additionally, we are proposing to remove this activity to align with recent FDA and CDC guidance, updating vaccination recommendations since the expiration of the COVID-19 Public Health Emergency (PHE). This updated guidance generally recommends vaccination for fewer people.[1,2]
Current Improvement Activity	
Current Activity ID:	**IA_PM_6**
Current Subcategory:	Population Management

Current Activity Title:	Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
Current Activity Description:	Address inequities in health outcomes by using population health data analysis tools to identify health inequities in the community and practice and assess options for effective and relevant interventions such as Population Health Toolkit or other resources identified by the clinician, practice, or by CMS. Based on this information, create, refine, and implement an action plan to address and close inequities in health outcomes and/or health care access, quality, and safety.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_3**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Current Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS-eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Removal Rationale:	We proposed the removal of this activity in the context of our regular review of the Improvement Activities Inventory. We are evolving the improvement activities Inventory to emphasize activities that demonstrably improve patient health outcomes while also encouraging the most efficient use of healthcare resources. Removal Criteria Factor 7, Activity is Obsolete, pertains to this activity removal proposal, as this activity does not reflect CMS' current high prioritization of measurable clinical outcomes as well as the topics of prevention, nutrition, and well-being. Additionally, we proposed to remove this activity to align with recent FDA and CDC guidance, updating vaccination recommendations since the expiration of the COVID-19 Public Health Emergency (PHE).[1,2] This updated guidance generally recommends vaccination for fewer people. We received public comments on these proposals. The following is a summary of the comments

	we received and our responses. *Comment*: Most commenters opposed the removal of eight improvement activities, stating that doing so could weaken progress toward inclusive, equitable care. A few commenters who opposed the proposal to remove the Achieving Health Equity subcategory stated that the removal of eight activities from the subcategory does not meet removal criteria under the "obsolete" designation, as they reflect current clinical best practices and were intentionally adopted to support improved patient health outcomes and advance whole-population health. Another commenter suggested meeting with interested parties to make changes as needed to retain certain improvement activities. A few commenters suggested maintaining or reclassifying IA_AHE_9, the only nutrition-focused activity, to ensure continued attention to food insecurity and nutrition risk. *Response*: We appreciate the public's input. Although we acknowledge the commenters' responses, we determined that these eight improvement activities met the criteria for removal under the "obsolete" removal criterion. These activities no longer align with the goals of other MIPS program components, such as the Quality performance category. Other available improvement activities better reflect current program priorities and initiatives, particularly those focused on prevention, nutrition, and well-being. Regarding IA_AHE_9, while we acknowledge the importance of nutrition, this specific improvement activity is not fully aligned with the shift in priorities to health, wellness, and prevention, although we do take note of this improvement activity's elements that can be integrated into the new health and wellness framework. As part of ongoing efforts to align all improvement activities with CMS's broader strategic priorities, we are refining the Inventory to focus on activities that promote whole-population health. This approach emphasizes prevention, wellness, and outcomes that benefit all patients across care settings, rather than initiatives targeted toward specific subpopulations. We thank the commenters for their suggestions, as indeed proper nutrition is fundamental to maintaining health, preventing chronic disease, and supporting resilience. We will consider how we can elevate nutrition as part of a broader wellness agenda to include in possible nutrition-oriented improvement activity development in future rulemaking. After consideration of public comments, we are finalizing the removal of the eight improvement activities as proposed.

[1] *https://www.nejm.org/doi/full/10.1056/NEJMsb2506929?logout=true.*
[2] *https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/your-health/end-of-phe.html.*

APPENDIX 3: MVP INVENTORY

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains three groups of MVP tables: Table 1: MVP Foundational Layer, Group A, which includes six new MVPs, and Group B, which includes modifications to 21 previously finalized MVPs. We received comments on Table 1, all Group A MVP tables, and 17 Group B MVP tables. Comment summaries and responses are included below Table 1 and after each set of applicable MVP table. We did not receive comments on the following previously finalized MVPs: B.6 Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes, B.8 Focusing on Women's Health, B.10 Improving Care for Lower Extremity Joint Repair, B.16 Quality Care for Patients with Neurological Conditions, or B.18 Quality Care in Mental Health and Substance Use Disorders. Comments not specific to the proposals to Group A or Group B MVPs are considered out of scope and are not addressed in this Appendix.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category relevant to the clinical specialty of the MVP. In addition, each MVP includes a foundational layer comprised of population health measures and Promoting Interoperability performance category objectives and measures. The foundational layer is the same for all MVPs.

We inadvertently omitted the Promoting Interoperability performance category optional ONC-ACB Surveillance Attestation from the MVP foundational layer in previous PFS final rule tables in Appendix 3. The ONC-ACB Surveillance Attestation has been an optional attestation for the Promoting Interoperability performance category since the first MIPS performance period in CY 2017 (81 FR 77019 through 77028). In the CY 2021 PFS final rule (85 FR 84849 through 84850), as a part of the MVP development criteria, we finalized that MVPs must include the full set of Promoting Interoperability performance category measures. In the CY 2022 PFS final rule (86 FR 65413), we stated that we do not intend to establish different reporting requirements for Promoting Interoperability measures in MVPs from what is established under traditional MIPS. As described at § 414.1365(c)(4)(i), an MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described under § 414.1375(b). For these reasons, we have added the optional ONC-ACB Surveillance Attestation described under § 414.1375(b)(3) to the foundational layer for all MVPs.

MVP Development: Performance Category Sources

The MVP tables contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities included in the MVP tables are located on the Quality Payment Program website and are as follows:

- Existing MIPS quality measures are in the 2025 MIPS Quality Measures List.[651] See Appendix 1: MIPS Quality Measures of this final rule for any additions (Table Group A), removals (Table Group C), or modifications to existing quality measures (Table Groups D and DD).

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[651] See the 2025 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3125/2025-MIPS-Quality-Measures-List.xlsx.*

● Existing QCDR measures are based on the most recent publication of the 2025 QCDR Measure Specification file.[652] We plan to modify the list of 2026 QCDR measures around December 2025.

● Existing improvement activities are in the 2025 Improvement Activities Inventory and the 2025 MIPS Data Validation Criteria.[653] See Appendix 2: Improvement Activities of this final rule for any additions (Table Group A), modifications to existing improvement activities (Table Group B), or removals (Table Group C).

● Existing cost measures are in the 2025 Cost Measures Inventory.[654] See Appendix 4: MIPS Cost Measures of this final rule for any modifications to existing cost measures (Group A).

● Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[655] See section IV.A.4.d.(4) of this final rule for any new measures or modifications to existing Promoting Interoperability measures.

● For further details on the population health measures (attributed to the quality performance category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).

MVP Development: Measure and Improvement Activities Updates and MVP Format Update

● We reformatted the MVP tables to stratify quality measures by clinical conditions and/or episodes of care for each MVP identified as "Clinical Groupings." When applicable, an "Advancing Health and Wellness" and/or "Experience of Care" clinical grouping is included for cross-cutting quality measures. This new stratified format offers a streamlined set of quality measures to aid clinicians in selecting the most clinically relevant measures applicable to their clinical area and identifies when quality and cost measures are linked.

● See Appendix 1: MIPS Quality Measures (Table Group C) of this final rule for removals of MIPS quality measures. The following MIPS quality measures were included in previously finalized MVPs and were proposed for removal from MIPS: Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use, Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer, Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease, Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients, Q419: Overuse of Imaging for the Evaluation of Primary Headache, Q424: Perioperative Temperature Management, Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females, Q487: Screening for Social Drivers of Health, Q498: Connection to Community Service Provider, and Q508: Adult COVID-19 Vaccination Status.

● See Appendix 2: Improvement Activities (Table Group C) of this final rule for removals of improvement activities. The following improvement activities were included in previously finalized MVPs and were proposed for removal from MIPS: IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, IA_AHE_8: Create and Implement an Anti-Racism Plan, IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, IA_AHE_11: Create and Implement a Plan to Improve Care for Lesbian,

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[652] See the 2025 QCDR Measure Specification file: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3108/2025_QCDR_Measure_Specifications_PUB.xlsx* for QCDR measures.

[653] See the 2025 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3131_duplicate/2025-Improvement-Activities-Inventory.zip* and 2025 MIPS Data Validation Criteria: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3203/2025-MIPS-Data-Validation-Criteria.zip. for improvement activity details.

[654] See the 2025 Cost Measures Inventory: https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2025.

[655] See the 2025 Promoting Interoperability Measure Specifications: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3122/2025-MIPS-Promoting-Interoperability-Measure-Specifications.zip for Promoting Interoperability measure details.

Gay, Bisexual, Transgender, and Queer Patients, IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health, IA_ERP_3: COVID-19 Clinical Data Reporting with or without Clinical Trial, IA_PM_6: Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities (Use of toolset or other resources to close healthcare disparities across communities), and IA_PM_26: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

● The following improvement activities are being removed from previously finalized MVPs as finalized in the CY 2025 PFS rule (89 FR 98411) beginning with the CY 2026 performance period/2028 MIPS payment year: IA_BMH_8: Electronic Health Record Enhancements for BH data capture, IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, IA_CC_2: Implementation of improvements that contribute to more timely communication of test results, and IA_PM_12: Population empanelment.

● Beginning with the CY 2026 performance period/2028 MIPS payment year, improvement activity IA_BE_4: Engagement of Patients through Implementation of New Patient Portal was modified as finalized in the CY 2025 PFS rule (89 FR 98411).

● The Achieving Health Equity (AHE) improvement activities subcategory was proposed for removal from MIPS. See Appendix 2: Improvement Activities (Table Groups B and C) of this final rule for any finalized modifications or removals to existing AHE subcategorized improvement activities.

● We proposed to no longer list IA_PCMH: Electronic submission of Patient Centered Medical Home Accreditation in each newly proposed or previously finalized MVP table. However, in accordance with § 414.1380(b)(3)(ii), MIPS eligible clinicians in a practice that are certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, may attest to this activity and receive an improvement activities performance category score of 100 percent (81 FR 77179 through 77180).

● We updated this appendix to include QCDR measures undergoing modifications planned by the QCDR measure stewards. When applicable and substantive in nature, we provided a brief overview of the planned modifications within applicable MVPs. Since QCDR measures are exempt from public notice and comment, this overview allowed for transparency with interested parties and an opportunity to comment on all aspects of each MVP prior to finalization. Final decisions to modify QCDR measure specifications are determined by QCDR measure stewards, separate from rulemaking, but may impact decisions as finalized in the final rule.

MVP Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables (Group A and Group B) below:

● Quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

● New MIPS quality and Promoting Interoperability measures finalized for inclusion in an MVP beginning with the CY 2026 performance period/2028 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1: MIPS Quality Measures: Table Group A of this final rule for further information regarding new MIPS quality measures. See section IV.A.4.d.(4) of this final rule for further information regarding new MIPS Promoting Interoperability performance category measures.

● Existing measures and improvement activities with finalized revisions are identified with a single asterisk (*). See Appendix 1: MIPS Quality Measures: Tables Group D and DD of this final rule for further information regarding finalized revisions to MIPS quality measures. See Appendix 2: Improvement Activities: Table Group B of this final rule for further information regarding finalized revisions to improvement activities. See Appendix 4: MIPS Cost Measures: Group A of this final rule for further information regarding finalized revisions to cost measures. See section IV.A.4.d.(4) of this final rule for further information regarding finalized revisions to Promoting Interoperability measures. We intend to include existing measures or activities with proposed revisions in MVPs (as applicable) regardless of whether the proposed revisions were finalized beginning with the CY 2026 performance period/2028 MIPS payment year, unless changes were required to continue to meet programmatic standards for inclusion.

● Quality measures and improvement activities identified with a double asterisk (**) can only be submitted when included in an MVP.

● Improvement activities that include an advancing health and wellness component are identified with an exclamation point (!) preceding the improvement activity ID.

● Quality measures considered high priority and/or outcome measures (as defined in § 414.1305) are identified in the Quality section of the new MVP table format. Further details of these types of measures are in the CMS Measures Management System Hub.[656] See section IV.A.4.d.(1)(b) of this final rule for further information regarding finalized revisions to the definition of a high priority measure.

● Quality measure collection types are identified in parentheses after each quality measure title.

Foundational Layer

Each MVP contains a foundational layer, which includes the entire set of Promoting Interoperability measures and two population health measures. The two population health measures are considered outcome measures as identified with a double exclamation mark (!!). The foundational layer is the same for all MVPs as listed in Table 1.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Caret symbol (^): new MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.

Table 1: MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups (Collection Type: Administrative Claims) **(*)(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	**(*) PI_PPHI_1:** Security Risk Analysis **(*) PI_PPHI_2:** High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide **PI_EP_1:** e-Prescribing **PI_EP_2:** Query of Prescription Drug Monitoring Program (PDMP) **PI_PEA_1:** Provide Patients Electronic Access to Their Health Information **PI_HIE_1:** Support Electronic Referral Loops By Sending Health Information AND **PI_HIE_4:** Support Electronic Referral Loops By Receiving and Reconciling Health Information OR **PI_HIE_5:** Health Information Exchange (HIE) Bi-Directional Exchange OR **PI_HIE_6:** Enabling Exchange Using the Trusted Exchange Framework and Common Agreement (TEFCA) **PI_PHCDRR_1:** Immunization Registry Reporting **PI_PHCDRR_2:** Syndromic Surveillance Reporting (Optional) **PI_PHCDRR_3:** Electronic Case Reporting **PI_PHCDRR_4:** Public Health Registry Reporting (Optional) **PI_PHCDRR_5:** Clinical Data Registry Reporting (Optional) **(^)(+) PI_PHCDRR_6:** Public Health Reporting Using TEFCA (Optional) **PI_ONCACB_1:** ONC-ACB Surveillance Attestation (Optional) **PI_INFBLO_1:** Actions to Limit or Restrict Compatibility or Interoperability of CEHRT Attestation **PI_ONCDIR_1:** ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A couple of commenters requested the removal of the population health measures as a foundational requirement as they believe these measures fail to accurately capture quality.

Response: The population health measures are part of the foundational layer included in all MVPs because they capture outcomes important to patients and provide meaningful information to clinicians so they can improve their practice. Although administrative claims measures use outcomes that are not directly reported by patients, they measure clinical outcomes that are central to patient well-being because avoidance of acute hospitalization is an important goal of care. Population health measurement is meant to be broadly applied to communities or populations and provide more uniformity in how the program measures population health, reduce clinician reporting burden, and focus on important public health priorities. To this end, these measures generate important feedback to help clinicians improve their practice and overall patient care. For further details on the population health measures included in the foundational layer, see CY 2022 PFS final rule (86 FR 65408 through 65409). We may consider updates through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Group A: New MVPs Proposed for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years
A.1 Diagnostic Radiology MVP

In the CY 2026 PFS proposed rule (90 FR 32352), we proposed and solicited comments on the Diagnostic Radiology MVP. The proposed Diagnostic Radiology MVP assesses meaningful outcomes in diagnostic radiology. This MVP would be most applicable to clinicians who treat patients within the practice of diagnostic radiology. The summary of the public comments received and our responses for this MVP are included immediately after Table A.1 and the list of improvement activities.

Quality Measures

We proposed to include six MIPS quality measures and three QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of diagnostic radiology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in diagnostic radiology:

- **Q145**: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy: This MIPS quality measure focuses on increasing clinician awareness of patient exposure to radiation in an effort to reduce potential harmful effects by requiring radiation exposure indices to be documented in all final reports.
- **Q360**: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies : This MIPS quality measure focuses on reducing the rate of unnecessary or repeat imaging studies by requiring clinicians to review and document a count of known CT and cardiac nuclear medicine studies the patient received within a 12-month period prior to the current study.
- **Q364**: Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: This MIPS quality measure ensures appropriate follow-up recommendations are documented for patients who have incidental pulmonary nodules found during CT imaging to either avoid unnecessary follow-up scans or identify early malignancies.
- **Q405**: Appropriate Follow-up Imaging for Incidental Abdominal Lesions: This MIPS quality measure ensures appropriate follow-up recommendations are documented for patients for whom incidental abdominal lesions are found during imaging studies to avoid unnecessary and costly follow-up procedures.
- **Q406**: Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients: This MIPS quality measure ensures appropriate follow-up recommendations are documented for patients for whom incidental thyroid nodules are found during imaging studies to avoid unnecessary and costly follow-up procedures.
- **Q494**: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level): This MIPS quality measure provides a method for monitoring and assessing appropriate radiation dose thresholds encouraging overall reductions in radiation dosage, an intermediate outcome directly and proportionally related to cancer prevention.
- **QMM17**: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS): This QCDR measure assesses for the use of standardized reporting of findings leading to more consistent

treatment recommendations, while also decreasing cost and inappropriate resource consumption.

- **QMM18**: Use of Breast Cancer Risk Score on Mammography: This QCDR measure ensures final reports for screening mammograms accurately include the breast cancer risk score and appropriate follow-up recommendations. This can be utilized to guide subsequent testing and treatment recommendations improving overall health outcomes.
- **QMM26**: Screening Abdominal Aortic Aneurysm Reporting with Recommendations: This QCDR measure ensures appropriate follow-up for an abdominal aortic aneurysm is documented in the final report by requiring radiologists to report recommendations consistently and in accordance with current guidelines, with direct communication as required. This QCDR measure has planned modifications including updates to the Society of Vascular Surgery guidelines referenced in the specification and modifications to denominator exceptions to address when screening is negative for abdominal aortic aneurysm (AAA), however, significant risk factors are present warranting future screening.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in diagnostic radiology, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_6**: Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BMH_12**: Promoting Clinician Well-Being
- **IA_CC_7**: Regular training in care coordination
- **IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_12**: Care coordination agreements that promote improvements in patient tracking across settings
- **IA_CC_19**: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1**: Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_2**: Participation in MOC Part IV
- **IA_PSPA_7**: Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12**: Participation in private payer CPIA

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of diagnostic radiology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in diagnostic radiology and aligns with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing diagnostic radiology care in inpatient hospitals.

Table A.1, followed by the list of improvement activities, represents the measures and activities finalized within the Diagnostic Radiology MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.1: Diagnostic Radiology MVP Clinical Groupings

Diagnostic Radiology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
General Diagnostic Radiology	**Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: MIPS CQM, Medicare Part B Claims)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies (Collection Type: MIPS CQM)	No	Yes	
	Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) (Collection Type: eCQM)	No	No	
Body Imaging (Thoracic/Abdominal)	**Q364:** Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines (Collection Type: MIPS CQM)	No	Yes	N/A
	Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	
	Q406: Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	
	QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS) (Collection Type: QCDR)	No	Yes	
Advancing Health and Wellness	**QMM18:** Use of Breast Cancer Risk Score on Mammography (Collection Type: QCDR)	No	Yes	N/A
	(*) QMM26: Screening Abdominal Aortic Aneurysm Reporting with Recommendations (Collection Type: QCDR)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Diagnostic Radiology Improvement Activities

- **IA_BE_6**: Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BMH_12**: Promoting Clinician Well-Being
- **IA_CC_7**: Regular training in care coordination
- **IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_12**: Care coordination agreements that promote improvements in patient tracking across settings
- **IA_CC_19**: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways

- **IA_PSPA_1**: Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_2**: Participation in MOC Part IV
- **IA_PSPA_7**: Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12**: Participation in private payer CPIA

The following is a summary of the comments we received and our responses.

Comment: Several commenters noted support for this MVP. A commenter believes this MVP offers a more targeted and relevant approach to quality reporting and that by aligning measures with clinical practice, it has the potential to reduce administrative burden and improve the accuracy of performance assessment. A commenter agreed with the improvement activities included in the MVP. Some commenters expressed concern with the limited number of applicable quality measures which may not provide enough participation opportunities, especially for small practices. A commenter recommended ACRad34: Multi-strata weighted average for 3 CT Exam Types, ACRad41: Use of Quantitative Criteria for Oncologic FDG PET Imaging, QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using O-Rads, and QMM18: Use of Breast Cancer Risk Score on Mammography be added to the MVP. Another commenter recommended MSN13: Screening Coronary Calcium Scoring for Cardiovascular Risk Assessment, Including Coronary Artery Calcification Regional Distribution Scoring, MSN15: Use of Thyroid Imaging Reporting & Data System (TI-RADS) in Final Report to Stratify Thyroid Nodule Risk, QMM19: DEXA/DXA and Fracture Risk Assessment for Patients with Osteopenia, QMM23: Low-Dose Cancer Screening Recommendation for CT and CTA of the Chest with Diagnosis of Emphysema, and QMM28: Reporting Breast Arterial Calcification (BAC) on Screening Mammography be included in this MVP. The commenter believes these measures focus on improving population health, preventative care, and chronic disease management.

Response: We thank the commenters for their support. We review and consider all feedback received during the development process, while factoring in program constraints and the goal to maintain stability within MVPs, which may contribute to the decision not to include a specific quality measure. We appreciate the suggestions for additional measures and may consider the inclusion of additional measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We understand that not all measures are applicable to all clinicians who would choose to report this MVP; however, reporting MVPs is voluntary at this time. Additionally, we encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years.

Comment: A commenter requested MSPB_1: Medicare Spending Per Beneficiary (MSPB) Clinician be removed from this MVP. Another commenter seeks guidance on how the proposed MSPB cost measure would apply to them, noting many radiologists practice in outpatient imaging centers and other non-inpatient settings. The commenter believes that with the MSPB cost measure radiologists could be assigned cost information inadvertently from attribution methodologies based on billing clinician and volume of services rendered.

Response: We believe that the MSPB Clinician cost measure is appropriate for use in this MVP and is the most applicable MIPS cost measure for individual diagnostic radiologists or their groups. Care provided by diagnostic radiologists can contribute to overall cost performance for inpatient hospitalizations, which is assessed by the MSPB Clinician measure. We note that MSPB Clinician is the most applicable MIPS cost measure for diagnostic radiologists.

Comment: A commenter expressed concern with the clinical groupings in this MVP and the alignment of performance measures with each specialty. The commenter's concern is this could result in a siloed approach and hinder collaboration among clinicians treating complex patients. The commenter recommended designing MVPs that encourage cross-specialty coordination to maintain quality and continuity of care.

Response: We appreciate the feedback regarding the clinical groupings. The purpose of the clinical groupings is to streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We encourage cross-specialty collaboration as any reporting clinician, sub-group, or group may report whichever four quality measures are most meaningful to their practice, regardless of clinical grouping. While the clinical groupings do not align with a requirement, they do help to visualize the full intent of the MVP by showing the internal structure, thereby also highlighting gaps in measures that can be added to the needs and priorities list.

Comment: A commenter expressed concerns with the inclusion of several radiation-related quality measures in MVPs. They believe Q145: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy is impractical and burdensome for groups with limited resources, Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: CT and Cardiac Nuclear Medicine Studies is difficult to implement

and track across sites with little clinical value, and Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Clinician Level) is faced with enterprise-wide technical barriers such as data access and unclear responsibility for reporting. A commenter expressed concern that Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT was included instead of ACRad34. Per the commenter, the National Quality Forum's Measure Applications Partnership report for 2023 rulemaking cycle identified Q494 and ACRad34 as complementary and not competing. The commenter believes ACRad34 will ensure broader participation, measure choice, and sustain progress in radiation dose optimization.

Response: We acknowledge the commenters' concerns and encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years. We understand that not all measures are applicable to all clinicians who would choose to report this MVP; however, reporting MVPs is voluntary at this time. This MVP reflects all applicable MIPS quality measures with additional QCDR measures that have been selected after our review and consideration of all feedback received during the development process, while factoring in program constraints and the goal to maintain stability within MVPs. We may consider the inclusion of additional measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Diagnostic Radiology MVP* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

A.2 Interventional Radiology MVP

In the CY 2026 PFS proposed rule (90 FR 32352), we proposed and solicited comments on the Interventional Radiology MVP. The proposed Interventional Radiology MVP assesses meaningful outcomes in interventional radiology. This MVP would be most applicable to clinicians who treat patients within the practice of interventional radiology. The summary of the public comments received and our responses for this MVP are included immediately after Table A.2 and the list of improvement activities.

Quality Measures

We proposed to include six MIPS quality measures and four QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of interventional radiology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in interventional radiology:

- **Q145**: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy: This MIPS quality measure focuses on increasing clinician awareness of patient exposure to radiation in an effort to reduce potential harmful effects by requiring radiation exposure indices to be documented in all final reports.
- **Q374**: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred clinician, closing the communication loop.
- **Q413**: Door to Puncture Time for Endovascular Stroke Treatment: This MIPS quality measure assesses for timely endovascular stroke treatment in ischemic stroke patients. Ensuring a door to puncture time of 90 minutes or less, gives stroke patients the best chance at functional recovery and improved health outcomes.
- **Q420**: Varicose Vein Treatment with Saphenous Ablation: Outcome Survey: This MIPS quality measure motivates clinicians to objectively quantify changes in quality of life after an ablation, the ultimate way to assess success of saphenous ablation for varicose veins.

- **Q421**: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal: This MIPS quality measure focuses on clinicians providing timely follow-up for patients with retrievable IVC filters to increase awareness of the potential harms of inappropriate continued inferior vena cava filtration in patients with retrievable filters.
- **Q465**: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries: This MIPS quality measure promotes successful treatment by ensuring documentation of delineation of all uterine arterial supply with embolization where possible, and appropriate embolization endpoints achieved which are indications of treatment efficacy.
- **RCOIR12**: Tunneled Hemodialysis Catheter Clinical Success Rate: This QCDR measure evaluates whether a tunneled central venous catheter has been successfully placed (or replaced) and ready for use within 72 hours after placement. This would ensure the catheter is operational and functional as quickly as possible and is tunneled to reduce complications.
- **RCOIR13**: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate: This QCDR measure evaluates success of percutaneous fistula creation for patients on maintenance hemodialysis, promoting the use of new technology with the potential to yield positive results such as fewer procedural complications.
- **RPAQIR14**: Arteriovenous Graft Thrombectomy Clinical Success Rate: This QCDR measure assesses clinical success of arteriovenous graft thrombectomy. Successful removal of a thrombosis supports continued use of the arteriovenous graft, reducing the need for additional vascular access procedures and allowing adequate dialysis to be performed.
- **RPAQIR15**: Arteriovenous Fistulae Thrombectomy Clinical Success Rate: This QCDR measure assesses clinical success of arteriovenous fistula thrombectomy. Arteriovenous fistulas can provide rapid extracorporeal blood flow that is necessary for hemodialysis and when feasible, are the preferred type of vascular access for chronic hemodialysis.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 19 improvement activities that reflect actions and processes undertaken by clinicians who specialize in interventional radiology, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_7:** Regular training in care coordination
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program

- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_25:** Cost Display for Laboratory and Radiographic Orders

Cost Measures

We are proposing to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of interventional radiology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in interventional radiology and aligns with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing interventional radiology care in inpatient hospitals.
- **COST_HAC_1:** Hemodialysis Access Creation: This MIPS episode-based cost measure assesses costs associated with the creation of graft or fistula access for long-term hemodialysis.
- **COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction**:** This MIPS episode-based cost measure assesses costs associated with the inpatient treatment for cerebral infarction or intracranial hemorrhage.

Table A.2, followed by the list of improvement activities, represents the measures and activities finalized within the Interventional Radiology MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.2: Interventional Radiology MVP Clinical Groupings

Interventional Radiology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Vascular	**(*) Q420:** Varicose Vein Treatment with Saphenous Ablation: Outcome Survey (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q421: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal (Collection Type: MIPS CQM)	No	No	
	Q465: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries (Collection Type: MIPS CQM)	No	Yes	
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
Neurological Intervention	**Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
General Interventional Radiology	**Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	No	

Interventional Radiology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_7:** Regular training in care coordination
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(*)(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways

- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_25:** Cost Display for Laboratory and Radiographic Orders

The following is a summary of the comments we received and our responses.

Comment: Several commenters noted support for this MVP. A commenter noted support for the Dialysis/Transplant clinical grouping in this MVP. A commenter appreciated the revised table format. A few commenters expressed concern with this MVP as they believe the current measure set only includes three broadly applicable quality measures, with the remainder focused on subspecialized areas such as stroke, dialysis access, and women's health. This narrow scope risks excluding many interventional radiologists from meaningful participation and may impose undue burden. The commenter requested the measure set be expanded to better reflect the diversity of interventional radiology practice and to reconsider the cost measures included, which may not fairly represent interventional radiology contributions. A commenter supported the inclusion of RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate and RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate. A commenter noted support for the improvement activities included in the MVP. A commenter recommended the addition of several quality measures including Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older, Q047: Advance Care Plan, Q130: Documentation of Current Medications in the Medical Record, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, Q355: Unplanned Reoperation within the 30-Day Postoperative Period, Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure, Q357: Surgical Site Infection (SSI), Q358: Patient-Centered Surgical Risk Assessment and Communication, Q404: Anesthesiology Smoking Abstinence, and Q418: Osteoporosis Management in Women Who Had a Fracture. The commenter also recommended the addition of IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.

Response: We thank the commenters for their support. Currently, reporting of MVPs is voluntary to allow for the flexibility of reporting via traditional MIPS in the instance an MVP does not fit a clinician's scope of care. However, we appreciate the suggestions for additional measures and would encourage the submission of meaningful new measures to the Annual Call for Measures for potential inclusion in future rulemaking. We may consider the inclusion of additional measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter expressed concern with the clinical groupings in this MVP and the alignment of performance measures with each specialty. The commenter's concern is this could result in a siloed approach and hinder collaboration among clinicians treating complex patients. The commenter recommended designing MVPs that encourage cross-specialty coordination to maintain quality and continuity of care. A commenter requested clarity on the formation of the clinical groupings, specifically their role in practices' participation, and plans for expanding the list of measures in each grouping.

Response: We appreciate the feedback regarding the clinical groupings. The purpose of the clinical groupings is to streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We encourage cross-specialty collaboration as any reporting clinician, sub-group, or group may report whichever four quality measures are most meaningful to their practice, regardless of clinical grouping. While the clinical groupings do not align with a requirement, they do help to visualize the full intent of the MVP by showing the internal structure, thereby also highlighting gaps in measures that can be added to the needs and priorities list. Using the MVP Maintenance Process, we encourage interested parties to submit recommended changes, including revisions to the clinical groupings.

Comment: A few commenters questioned the validity of including the MSPB_1: Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as they do not believe interventional radiologists typically meet the intent of the measure as they are not generally the primary providers managing the patients' care. Another commenter is concerned with the inclusion of COST_HAC_1: Hemodialysis Access Creation and COST_IHCI_1: Intracranial Hemorrhage or Cerebral Infarction. The commenter believes COST_HAC_1 and COST_IHCI_1 are based on care episodes where interventional radiologists are frequently part of a multi-specialty care team and have limited control of the management of the care episode.

Response: We believe that the Hemodialysis Access Creation, Intracranial Hemorrhage or Cerebral Infarction, and Medicare Spending Per Beneficiary (MSPB) Clinician cost measures are appropriate for use in this MVP, as these

measures may be attributed to individual interventional radiologists or their groups. Care provided by interventional radiologists can contribute to overall cost performance for inpatient hospitalizations, hemodialysis access creation, or treatment of intracranial hemorrhage or cerebral infarction, which are assessed by the measures in this MVP.

After consideration of public comments, we are finalizing the *Interventional Radiology MVP* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

A.3 Neuropsychology MVP

In the CY 2026 PFS proposed rule (90 FR 32352), we proposed and solicited comments on the Neuropsychology MVP. The proposed Neuropsychology MVP focuses on the clinical specialty of providing treatment and management of neuropsychological care. This MVP would be most applicable to clinicians who treat patients within the practice of neuropsychology, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.3 and the list of improvement activities.

Quality Measures

We proposed to include six MIPS quality measures and three QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of neuropsychology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in neuropsychology:

- **Q282**: Dementia: Functional Status Assessment: This MIPS quality measure evaluates for the performance of a functional status assessment for patients diagnosed with dementia.
- **Q286**: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: This MIPS quality measure assesses for the discussion of safety concerns with either the patients diagnosed with dementia or their caregivers. There are two domains of safety that should be addressed to meet performance of the measure which include dangerousness to self or others and environmental risks. If a risk is discovered, it is anticipated that the clinician would document mitigation recommendations to promote safety outcomes for these patients.
- **Q288**: Dementia: Education and Support of Caregivers for Patients with Dementia: This MIPS quality measure ensures clinician communication of education on dementia disease management and health behavior with the added support of referrals to additional support resources for patients diagnosed with dementia and their caregivers.
- **MBHR13**: Social Role Functioning Assessment utilizing PROMIS Adult Ability to Participate in Social Roles and Activities: This QCDR measure ensures patients who report concerns related to their psychosocial function are assessed, and a follow-up plan is documented for those patients who may have difficulty with social role function and their ability to effectively participate in one's usual role.
- **MBHR15:** Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment: This QCDR measure ensures patients are referred for evaluation due to concerns for cognitive changes or difficulties receive a standardized valid assessment of cognition with results documented, including documentation of provider's consideration of relevant cultural-linguistic and demographic factors that may have affected assessment and resulting assessment.

- **MBHR18**: Provision of Feedback Following a Cognitive or Mental Status Assessment with Documentation of Understanding of Test Results and Subsequent Healthcare Plan with Timely Transmission of Results: This QCDR measure ensures patients who receive a standardized cognitive or mental status assessment engage in a post-evaluation feedback session(s) so they may better understand their medical condition and prognosis. This drives improved health outcomes through improved patient participation in treatment planning and assists them with making necessary lifestyle adjustments.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in neuropsychology. The quality measures below assess for age-specific screenings and follow-up actions for select measures:

- **Q130**: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- **Q134**: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- **Q181**: Elder Maltreatment Screen and Follow-up Plan: This MIPS quality measure ensures routine screening for potential elder maltreatment and is an essential strategy for guarding older adults from abuse and neglect.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 10 improvement activities that reflect actions and processes undertaken by clinicians who specialize in neuropsychology, as well as activities that promote advancing health and wellness, engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_22:** Improved Practices that Engage Patients Pre-Visit
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_21:** Advance Care Planning

Cost Measures

We proposed to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of neuropsychology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in neuropsychology, including:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in neuropsychology care in inpatient hospitals.
- **TPCC_1:** Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers. Neuropsychologists are included in attribution for the TPCC measure as they may provide broad, ongoing care to their patients, which is in line with the intent of the TPCC measure.

Table A.3, followed by the list of improvement activities, represents the measures and activities finalized within the Neuropsychology MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.3: Neuropsychology MVP Clinical Groupings

Neuropsychology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Neurodegenerative Disorders	**Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
	Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q181: Elder Maltreatment Screen and Follow-up Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	

Neuropsychology Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_22:** Improved Practices that Engage Patients Pre-Visit
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_21:** Advance Care Planning

The following is a summary of the comments we received and our responses.

Comment: Several commenters noted support for this MVP. A commenter appreciated the revised table format. A commenter supported the inclusion of Q282, Q286, and Q288 as they believe it encourages functional assessment, safety concern and screening, and education and support of caregivers which are appropriate to ensure meaningful and comprehensive assessment of patients living with dementia. The commenter also supported the inclusion of MBHR13, MBHR15, and MBHR18, which they believe are critical to ensuring accurate assessment, decreasing health disparities, and encouraging timely follow-up to improve outcomes of individuals living with dementia. Several commenters recommended adding MBHR11 and MBHR16, noting that neuropsychologists serve diverse populations across the lifespan and these measures are critical for capturing quality of care beyond dementia. A commenter recommended adding Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter noted disappointment with what they perceived as a lack of transparency and collaboration in developing this MVP.

Response: We post MVP candidates to the Quality Payment Program website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: A commenter expressed concern with the clinical groupings in this MVP and the alignment of performance measures with each specialty. The commenter's concern is this could result in a siloed approach and hinder collaboration among clinicians treating complex patients. The commenter recommended designing MVPs that encourage cross-specialty coordination to maintain quality and continuity of care.

Response: We appreciate the feedback regarding the clinical groupings. The purpose of the clinical groupings is to streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We encourage cross-specialty collaboration as any reporting clinician, sub-group, or group may report whichever four quality measures are most meaningful to their practice, regardless of clinical grouping. While the clinical groupings do not align with a requirement, they do help to visualize the full intent of the MVP by showing the internal structure, thereby also highlighting gaps in measures that can be added to the needs and priorities list. Using the MVP Maintenance Process, we encourage interested parties to submit recommended changes, including revisions to the clinical groupings.

After consideration of public comments, we are finalizing the *Neuropsychology MVP* with modifications in Table A.3 for the CY 2026 performance period/2028 MIPS payment year and future years. However, we are not finalizing the inclusion of MBHR13: Social Role Functioning Assessment utilizing PROMIS Adult Ability to Participate in Social Roles and Activities as it did not meet the fully developed and tested criteria due to a lack of data, which resulted in no empirical validity. In addition, we are not finalizing the inclusion of MBHR15: Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment as this is a process-based measure and does not align with our goal of prioritizing outcome measures and reducing the number of process-based quality measures in MIPS. Additionally, this measure concept represents a single aspect of cognitive assessments, We would encourage the combining of similar measure concepts into a single more robust measure. Lastly, we are not finalizing MBHR18: Provision of Feedback Following a Cognitive or Mental Status Assessment with Documentation of Understanding of Test Results and Subsequent Healthcare Plan with Timely Transmission of Results as the measure did not meet the criteria for inclusion in MIPS as there was no evidence of a gap in care, outlined within the CY 2021 Medicare PFS Final Rule [§ 414.1400(b)(4)(iv)(G)].

A.4 Pathology MVP

In the CY 2026 PFS proposed rule (90 FR 32352), we proposed and solicited comments on the Pathology MVP. The proposed Pathology MVP focuses on assessing meaningful outcomes in pathology. This MVP would be most applicable to pathology clinicians. The summary of the public comments received and our responses for this MVP are included immediately after Table A.4 and the list of improvement activities.

Quality Measures

We proposed to include seven MIPS quality measures and seven QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of pathology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in pathology:

- **Q249**: Barretts Esophagus: This MIPS quality measure assesses appropriate and complete final report documentation to ensure accurate diagnoses.

- **Q250**: Radical Prostatectomy Pathology Reporting: This MIPS quality measure ensures that pathology reports include all appropriate information as having a complete set of pathology descriptors is crucial for staging and subsequent therapeutic decisions.
- **Q395**: Lung Cancer Reporting (Biopsy/Cytology Specimens): This MIPS quality measure encourages pathologists to further classify tumors into a more specific histologic subtype thereby reducing the use of the term non-small-cell lung cancer not otherwise specified (NSCLC-NOS) and furnishing uniform terminology and diagnostic criteria based on an integrated multidisciplinary platform.
- **Q396**: Lung Cancer Reporting (Resection Specimens): This MIPS quality measure assesses for standardized final reports for lung biopsy and cytology specimens with a diagnosis of primary non-small cell lung cancer allowing for classification to be based on an integrated multidisciplinary platform.
- **Q397**: Melanoma Reporting: This MIPS quality measure assesses final reports to ensure alignment with guidelines and inclusion of all appropriate tumor characteristics for more precise staging, improving treatment outcomes.
- **Q440**: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician: This MIPS quality measure ensures timely reporting of pathology results to mitigate delays in treatment.
- **Q491**: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status: This MIPS quality measure assesses for guideline recommended MMR/MSI testing for patients considering checkpoint inhibitor therapy, which aims to improve health outcomes by making care more targeted.
- **CAP30**: Urinary Bladder Cancer: Complete Analysis and Timely Reporting: This QCDR measure assesses all pathology cancer reports to ensure they are complete, contain all necessary data elements and are returned within a maximum of two business days. By mandating a thorough report in a timely fashion, this measure encourages appropriate and quick treatment.
- **CAP34**: Molecular Assessment: Biomarkers in Non-Small Cell Lung Cancer: This QCDR measure ensures pathology reports for non-small cell lung cancer (NSCLC) contain impression or recommendation for biomarker mutation testing. Accurate reporting allows patients to receive matched targeted therapy.
- **CAP40**: Squamous Cell Skin Cancer: Complete Reporting: This QCDR measure assesses pathology reports for completeness of histologic findings, including margin status degree of differentiation/histologic grade, depth or level of invasion, presence of perineural invasion, tumor diameter, and presence of lymphovascular invasion which are vital in creating treatment and follow-up plans.
- **QMM21**: Incorporating results of concurrent studies into Final Reports for Bone Marrow Aspirate of patients with Leukemia, Myelodysplastic syndrome, or Chronic Anemia: This QCDR measure ensures that all final bone marrow reports contain results of concurrent studies performed as well as an interpretation of those results, thereby improving patient outcomes and continuity of care.
- **QMM25**: Use of Structured Reporting for Urine Cytology Specimens: This QCDR measure ensures uniformity and reproducibility in the reporting of urine cytology through standardization by requiring use of The Paris System.
- **QMM29**: Use of Appropriate Classification System for Lymphoma Specimen: This QCDR measure encourages precise classification of lymphoma by ensuring results are accurately and effectively interpreted by the treating clinician.
- **QMM30**: Appropriate Use of Bethesda System for Reporting Thyroid Cytopathology on Fine Needle Aspirations (FNA) of Thyroid Nodule(s): This QCDR measure encourages results from FNA of thyroid nodules are properly and uniformly categorized by using the Bethesda System for Reporting Thyroid Cytopathology.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 13 improvement activities that reflect actions and processes undertaken by clinicians who specialize in pathology, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_2:** Participation in MOC Part IV
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **IA_PSPA_35:** Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of pathology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in pathology and align with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing pathology care in inpatient hospitals.

Table A.4, followed by the list of improvement activities, represents the measures and activities finalized within the Pathology MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component

Table A.4: Pathology MVP Clinical Groupings

Pathology MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Pathology	**Q249:** Barrett's Esophagus (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	N/A
	Q250: Radical Prostatectomy Pathology Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	N/A
	Q396: Lung Cancer Reporting (Resection Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q397: Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	N/A
	Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	No	Yes	
	Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status (Collection Type: MIPS CQM)	No	Yes	
	CAP30: Urinary Bladder Cancer: Complete Analysis and Timely Reporting (Collection Type: QCDR)	No	Yes	
	CAP34: Molecular Assessment: Biomarkers in Non-Small Cell Lung Cancer (Collection Type: QCDR)	No	Yes	
	CAP40: Squamous Cell Skin Cancer: Complete Reporting (Collection Type: QCDR)	No	Yes	
	QMM21: Incorporating results of concurrent studies into Final Reports for Bone Marrow Aspirate of patients with Leukemia, Myelodysplastic syndrome, or Chronic Anemia (Collection Type: QCDR)	No	Yes	
	QMM25: Use of Structured Reporting for Urine Cytology Specimens (Collection Type: QCDR)	No	Yes	
	QMM29: Use of Appropriate Classification System for Lymphoma Specimen (Collection Type: QCDR)	No	Yes	
	QMM30: Appropriate Use of Bethesda System for Reporting Thyroid Cytopathology on Fine Needle Aspirations (FNA) of Thyroid Nodule(s)	No	Yes	

Pathology MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: QCDR)			

Pathology Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_2:** Participation in MOC Part IV
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **(*) IA_PSPA_35:** Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data

The following is a summary of the comments we received and our responses.

Comment: Several commenters noted support for this MVP. A commenter appreciated the revised table format. A commenter recommended the addition of CAP41: Basal Cell Skin Cancer: Complete Reporting, CAP22: Biopsy Reporting Time to Clinician and CAP38: Prostate Cancer Reporting: Complete Analysis.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter expressed concern with the clinical groupings in this MVP and the alignment of performance measures with each specialty. The commenter's concern is this could result in a siloed approach and hinder collaboration among clinicians treating complex patients. The commenter recommended designing MVPs that encourage cross-specialty coordination to maintain quality and continuity of care.

Response: We appreciate the feedback regarding the clinical groupings. The purpose of the clinical groupings is to streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We encourage cross-specialty collaboration as any reporting clinician, sub-group, or group may report whichever four quality measures are most meaningful to their practice, regardless of clinical grouping. While the clinical groupings do not align with a requirement, they do help to visualize the full intent of the MVP by showing the internal structure, thereby also highlighting gaps in measures that can be added to the needs and priorities list. Using the MVP Maintenance Process, we encourage interested parties to submit recommended changes, including revisions to the clinical groupings.

Comment: A commenter is concerned that this MVP covers a broad specialty area and there may be physicians with narrower subspecialties that are unable to report this MVP.

Response: Currently, reporting of MVPs is voluntary to allow for the flexibility of reporting via traditional MIPS in the instance an MVP does not fit a clinician's scope of care. However, we would encourage the submission of meaningful new measures to the Annual Call for Measures for potential inclusion in future rulemaking. We may consider the inclusion of additional measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Pathology MVP* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

A.5 Podiatry MVP

In the CY 2026 PFS proposed rule (90 FR 32352), we proposed and solicited comments on the Podiatry MVP. The proposed Podiatry MVP focuses on assessing meaningful outcomes in foot and ankle care for patients with chronic conditions, wound/ulcers, and general care for the podiatry patient. This MVP would be most applicable to podiatry clinicians, including NPPs such as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.5 and the list of improvement activities.

Quality Measures

We proposed to include 7 MIPS quality measures and 10 QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of podiatry. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in podiatry:

- **Q126**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: This MIPS quality measure ensures patients diagnosed with diabetes mellitus have a lower extremity neurological exam performed at least once every 12 months.
- **Q127**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear: This MIPS quality measure ensures patients diagnosed with diabetes mellitus are evaluated for proper footwear and sizing at least once every 12 months.
- **Q374**: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- **REGCLR5**: Offloading with Remote Monitoring: This QCDR measure evaluates patient compliance with prescribed off-loading via remote monitoring and compliance being demonstrated as complete healing of the ulcer within 10 weeks. The monitoring of patient adherence enables the clinician to intervene when a patient is non adherent.
- **REGCLR8**: Monitor and Improve Treatment Outcomes in Chronic Wound Healing: This QCDR measure ensures patients with chronic non-healing wounds are re-assessed and experience an improved healing rate after a change in treatment plan based upon information learned from the re-assessment. Improved wound healing rates may reduce spending on advanced treatments.
- **USWR22**: Nutritional Assessment and Intervention Plan in patients with Wounds and Ulcers: This QCDR measure ensures patients with wounds and/or ulcers complete a validated nutritional assessment and receive an appropriate intervention plan based on the results. Evidence suggests that oral nutritional supplements, particularly with high protein content, can reduce the risk of developing pressure ulcers.
- **USWR32**: Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply: This QCDR measure assesses for adequate compression at each visit for treating patients with venous leg ulcers. This measure

establishes the requirement of safe, effective, and consistent compression treatment of VLUs.

- **USWR33**: Diabetic Foot Ulcer (DFU) Healing or Closure: This QCDR measure evaluates achieved healing or closure of diabetic foot ulcers within 6 months stratified by the Wound Healing Index (WHI). Reporting of healing rates stratified by the WHI makes it possible to see individual variations in quality between clinicians and compare performance based on similar wound severity.
- **USWR34**: Venous Leg Ulcer (VLU) Healing or Closure: This QCDR measure evaluates achieved healing or closure of venous leg ulcers (VLU) within 12 months stratified by the Wound Healing Index (WHI). Reporting VLU healing stratified by the WHI enables honest reporting of VLU healing rates and fair comparison of clinician performance.
- **USWR35**: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer: This QCDR measure assesses for adequate off-loading for diabetic foot ulcers during patient visits. Adequate off-loading increases the likelihood of DFU healing.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in podiatry care. The measures assess for age-specific screenings and follow-up actions for select measures:

- **Q155**: Falls: Plan of Care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.
- **Q226**: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure ensures all adult patients are screened for high blood pressure and have a recommended follow-up plan if blood pressure is elevated or hypertensive.
- **Q358**: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures patients receive a personalized surgical risk assessment completed using a validated risk calculator or multi-institutional clinical data prior to the surgery with discussion of the identified risks with the surgeon.
- **MEX5**: Hammer Toe Outcome: This QCDR measure addresses pain caused by toe deformity and ensures appropriate intervention for pain reduction. Lesser toe deformities are common and can have a significant impact on the function of the foot and quality of life. Appropriate intervention can result in improvements in activities of daily living and quality of life.
- **REGCLR1**: Heel Pain Treatment Outcomes for Adults: This QCDR measure addresses heel pain and ensures appropriate intervention for pain reduction. Clinical practice guideline suggests that treatment needs to be properly tailored to the patient based upon the cause of the pain.
- **REGCLR3**: Bunion Outcome - Adult and Adolescent: This QCDR measure addresses bunion pain and ensures appropriate intervention for pain reduction. Alleviation of bunion pain can result in improvement in activities of daily living and quality of life.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 10 improvement activities that reflect actions and processes undertaken by clinicians who specialize in podiatry care, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared

decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_22:** CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of podiatry care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in podiatry and align with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing podiatry care in inpatient hospitals.

Table A.5, followed by the list of improvement activities, represents the measures and activities finalized within the Podiatry MVP.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.5: Podiatry MVP Clinical Groupings

Podiatry MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Chronic Conditions	**Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (Collection Type: MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q127: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (Collection Type: MIPS CQM)	No	No	

Podiatry MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Wound/Ulcer	**REGCLR5:** Offloading with Remote Monitoring (Collection Type: QCDR)	Yes	Yes	N/A
	REGCLR8: Monitor and Improve Treatment Outcomes in Chronic Wound Healing (Collection Type: QCDR)	Yes	Yes	
	USWR32: Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply (Collection Type: QCDR)	Yes	Yes	
	USWR33: Diabetic Foot Ulcer (DFU) Healing or Closure (Collection Type: QCDR)	Yes	Yes	
	USWR34: Venous Leg Ulcer (VLU) Healing or Closure (Collection Type: QCDR)	Yes	Yes	
	USWR35: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer (Collection Type: QCDR)	No	No	
General Podiatry	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: MIPS CQM, eCQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**Q155:** Falls: Plan of Care (Collection Type: MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	
	MEX5: Hammer Toe Outcome (Collection Type: QCDR)	Yes	Yes	N/A
	REGCLR1: Heel Pain Treatment Outcomes for Adults (Collection Type: QCDR)	Yes	Yes	
	REGCLR3: Bunion Outcome - Adult and Adolescent (Collection Type: QCDR)	Yes	Yes	

Podiatry Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_22:** CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship

The following is a summary of the comments we received and our responses.

Comment: Several commenters noted support for this MVP. A commenter appreciated the revised table format. A couple of commenters supported the inclusion of USWR22: Nutrition Assessment and Intervention Plan for patients with wounds and ulcers.

Response: We thank the commenters for their support.

Comment: A commenter expressed concern with the clinical groupings in this MVP and the alignment of performance measures with each specialty. The commenter's concern is this could result in a siloed approach and hinder collaboration among clinicians treating complex patients. The commenter recommended designing MVPs that encourage cross-specialty coordination to maintain quality and continuity of care.

Response: We appreciate the feedback regarding the clinical groupings. The purpose of the clinical groupings is to streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We encourage cross-specialty collaboration as any reporting clinician, sub-group, or group may report whichever four quality measures are most meaningful to their practice, regardless of clinical grouping. While the clinical groupings do not align with a requirement, they do help to visualize the full intent of the MVP by showing the internal structure, thereby also highlighting gaps in measures that can be added to the needs and priorities list. Using the MVP Maintenance Process, we encourage interested parties to submit recommended changes, including revisions to the clinical groupings.

Comment: A couple of commenters expressed concern that many of the measures included in this MVP are topped out, making it very difficult for podiatrists to perform well under this model. Another commenter expressed concern with the limited number of quality measures available in this MVP.

Response: We acknowledge the commenters' concerns and encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years. While we endeavor to include measures that allow for maximum points, we want to ensure important aspects of care within the MVP clinical topic are represented.

After consideration of public comments, we are finalizing the *Podiatry MVP* with modifications in Table A.5 for the CY 2026 performance period/2028 MIPS payment year and future years. We are not finalizing the inclusion of USWR22: Nutritional Assessment and Intervention Plan in patients with Wounds and Ulcers as CMS has rejected this QCDR measure for the 2026 MIPS performance period because the QCDR measure doesn't meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years [§42 CFR 414.1400(b)(4)(iv)(J)].

A.6 Vascular Surgery MVP

In the CY 2026 PFS proposed rule (90 FR 32352), we proposed and solicited comments on the Vascular Surgery MVP. The proposed Vascular Surgery MVP focuses on the clinical specialty of surgery. This MVP would be most applicable to clinicians who treat patients within the surgical settings of vascular surgery, including NPPs such as nurse practitioners, and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.6 and the list of improvement activities.

Quality Measures

We proposed to include 13 MIPS quality measures and 4 QCDR measures within the quality performance category of this MVP, which are specific to the clinical specialty of surgery. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care provided by clinicians who specialize in surgery:

- **Q259**: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2): This MIPS quality measure ensures patients are selected appropriately for these procedures to limit experience of major complications, evidenced by discharge home no later than post-operative day number 2.
- **Q344**: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post- Operative Day #2): This MIPS quality measure ensures patients are selected appropriately for these procedures to limit experience of major complications, evidenced by discharge home no later than post-operative day number 2.
- **Q355**: Unplanned Reoperation within the 30-Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.
- **Q356**: Unplanned Hospital Readmission within 30 Days of Principal Procedure: This MIPS quality measure ensures evaluation of any unexpected surgical complications or adverse outcomes evidenced by unplanned hospital re-admission within 30 days of the principal surgical procedure.
- **Q357**: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.
- **Q374**: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- **RCOIR12**: Tunneled Hemodialysis Catheter Clinical Success Rate: This QCDR measure ensures patients with tunneled central venous access catheter insertions or replacements for ESRD on maintenance dialysis receive full dialysis treatment as prescribed within 72 hours of catheter placement or exchange.
- **RCOIR13**: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate: This QCDR measure ensures percutaneous created arteriovenous fistulas for patients on dialysis are deemed ready for use with at least 2 16-gauge needles for 3 consecutive dialysis treatments at prescribed blood flow rates.
- **RPAQIR14**: Arteriovenous Graft Thrombectomy Clinical Success Rate: This QCDR measure ensures clinical success of arteriovenous graft (AVG) thrombectomies for patients on maintenance dialysis evidenced by successful first dialysis treatment following the thrombectomy with needles using that access.
- **RPAQIR15**: Arteriovenous Fistulae Thrombectomy Clinical Success Rate: This QCDR measure ensures clinical success of arteriovenous fistulae (AVF) thrombectomies for patients on maintenance dialysis evidenced by successful first dialysis treatment following the thrombectomy with needles using that access.

The following broadly applicable MIPS quality measures are relevant to clinicians who treat patients in surgical settings. The measures assess for age-specific screenings and follow-up actions for select measures:

- **Q001**: Diabetes: Glycemic Status Assessment Greater Than 9%: This inverse outcome MIPS quality measure assesses diabetic patients for poor control of their HbA1c.
- **Q047**: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.

- **Q130**: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- **Q226**: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- **Q321**: CAHPS for MIPs Clinician/Group Survey: This survey would provide direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.
- **Q358**: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures patients receive a personalized surgical risk assessment completed using a validated risk calculator or multi-institutional clinical data prior to the surgery with discussion of the identified risks with the surgeon.
- **Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 16 improvement activities that reflect actions and processes undertaken by surgical care clinicians, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making.
- **IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_2:** Anticoagulant Management Improvements
- **IA_PM_5:** Engagement of community for health status improvement
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.

Cost Measures

We proposed to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical specialty of surgical care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide

a meaningful assessment of the clinical care for clinicians who specialize in surgical care and align with other measures and activities within this MVP:

- **COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia: This MIPS episode-based cost measure assesses costs associated with elective revascularization surgery for lower extremity chronic critical limb ischemia.
- **COST_HAC_1:** Hemodialysis Access Creation: This MIPS episode-based cost measure assesses costs associated with the creation of graft or fistula access for long-term hemodialysis.
- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those who treat patients within vascular surgery.

Table A.6, followed by the list of improvement activities, represents the measures and activities finalized within the Vascular Surgery MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

Table A.6: Vascular Surgery MVP Clinical Groupings

Vascular Surgery MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Interventional	**Q259:** Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non- Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2) (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post- Operative Day #2) (Collection Type: MIPS CQM)	Yes	Yes	
Surgical	**Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQM)	Yes	Yes	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	Yes	Yes	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Vascular Surgery MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	Yes	Yes	
General Vascular Surgery	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	No	No	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q321: CAHPS for MIPs Clinician/Group Survey (Collection Type: CSV)	No	Yes	
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	

Vascular Surgery Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination

- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(*)(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_2:** Anticoagulant Management Improvements
- **(!) IA_PM_5:** Engagement of community for health status improvement
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization

The following is a summary of the comments we received and our responses.

Comment: Several commenters noted support for this MVP. A commenter noted support for the Dialysis/Transplant clinical grouping in this MVP. A commenter appreciated the revised table format. A commenter supported the inclusion of RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate and RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate. Another commenter supported the inclusion of Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. A commenter recommended the addition of Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this MVP. Another commenter requested the addition of Q145: Radiology: Exposure Dose Indices for Procedures Using Fluoroscopy, Q420: Varicose Vein Treatment with Saphenous Ablation: Outcome Survey, Q421: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal, and Q465: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries. The commenter believes these measures are relevant to independent vascular surgeons and focus on patient outcomes and safety without creating excessive data reporting burden.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures or the removal of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter expressed concern with the clinical groupings in this MVP and the alignment of performance measures with each specialty. The commenter's concern is this could result in a siloed approach and hinder collaboration among clinicians treating complex patients. The commenter recommended designing MVPs that encourage cross-specialty coordination to maintain quality and continuity of care.

Response: We appreciate the feedback regarding the clinical groupings. The purpose of the clinical groupings is to streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We encourage cross-specialty collaboration as any reporting clinician, sub-group, or group may report whichever four quality measures are most meaningful to their practice, regardless of clinical grouping. While the clinical groupings do not align with a requirement, they do help to visualize the full intent of the MVP by showing the internal structure, thereby also highlighting gaps in measures that can be added to the needs and priorities list. Using the MVP Maintenance Process, we encourage interested parties to submit recommended changes, including revisions to the clinical groupings.

After consideration of public comments, we are finalizing the *Vascular Surgery MVP* as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

Group B: Modifications to Previously Finalized MVPs for the CY 2026 Performance Period/2028 MIPS Payment Year and Future Years

B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

The B.1 table, followed by a list of improvement activities, represents the measures and activities finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP (89 FR 99006 through 99009) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP focuses on important assessors of the care emergency clinicians provide to patients. By focusing on these specific measures and activities, emergency clinicians can reduce clinical variability, improve the quality of emergency care and potentially lower costs. This MVP would be most applicable to clinicians who treat patients within the practice of emergency medicine, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.1 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[657], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measure[658]:

- **HCPR24**: Appropriate Utilization of Vancomycin for Cellulitis: This QCDR measure is undergoing modifications to clarify the numerator and add definitions for patients with known Methicillin-resistant Staphylococcus aureus (MRSA) infection or risks for MRSA infection.

Improvement Activities

For the reasons stated in the introduction of this appendix[659], we removed three improvement activities from this MVP: **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Clinical Groupings

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[657] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[658] Ibid.
[659] Ibid.

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Infectious Disease/ Antibiotic Stewardship	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_EDV_1:** Emergency Medicine
	Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQM)	No	Yes	
	Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	No	Yes	
	(*) HCPR24: Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	No	Yes	
Trauma	**Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQM)	No	Yes	**COST_EDV_1:** Emergency Medicine
	Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQM)	No	Yes	
Orthopedic Emergencies	**ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain (Collection Type: QCDR)	No	Yes	**COST_EDV_1:** Emergency Medicine
	ECPR46: Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR)	No	Yes	
Experience of Care	**Q321:** CAHPS for MIPs Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	**COST_EDV_1:** Emergency Medicine
	ACEP50: ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR)	Yes	Yes	

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BMH_12:** Promoting Clinician Wellbeing
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(!) IA_PSPA_15:** Implementation of an ASP

The following is a summary of the comments we received and our responses.

Comment: A commenter noted support for the proposed maintenance updates to this MVP. A commenter requested the addition of Q066: Appropriate Testing for Pharyngitis, Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy, and Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis to this MVP. These measures are included in the MIPS Emergency Medicine Specialty Set and are relevant to emergency medicine. Together, these measures target the critical goal of ensuring appropriate use of antibiotics. The commenter believes the addition of these measures would ensure this MVP more accurately reflects the practice of emergency clinicians and would help to incentivize participation in this MVP.

Response: We thank the commenter for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.2: Advancing Cancer Care MVP

The B.2 table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Cancer Care MVP (89 FR 99009 through 99015) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Advancing Cancer Care MVP focuses on the clinical specialty of providing fundamental treatment and management of cancer care. This MVP would be most applicable to clinicians who treat patients within the practice of oncology and hematology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.2 and the list of improvement activities.

Quality Measures

We proposed adding two QCDR measures:

- **PIMSH15**: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents in the Infusion Center - Avoidance of Overuse (Lower Score - Better): This QCDR measure is an inverse measure (lower score is better) that ensures clinicians follow clinical guidelines for patients treated with low- or minimal-emetic-risk antineoplastic agents by assessing for inappropriate pre-treatment antiemetic therapy.
- **PIMSH16**: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents in the Infusion Center: This QCDR measure ensures clinicians follow clinical guidelines for patients treated with high- or moderate-emetic-risk antineoplastic agents by assessing for appropriate pre-treatment antiemetic therapy, which could result in improved control of nausea and vomiting in patients.

For the reasons stated in the introduction of this appendix[660], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measure[661]:

- **PIMSH13:** Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy: This QCDR measure is undergoing modifications to add a denominator note to clarify the appropriate timeframe for the denominator eligible diagnosis ensuring consistent denominator eligible identification.

Improvement Activities

For the reasons stated in the introduction of this appendix[662], we removed three improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and **IA_PM_26**: Vaccine

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[660] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[661] Ibid.
[662] Ibid.

Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.2: Advancing Cancer Care MVP Clinical Groupings

Advancing Cancer Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Medical Oncology	**(*) Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQM)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
	(*) Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQM)	No	No	
	Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	No	No	**COST_PC_1:** Prostate Cancer **(*) TPCC_1:** Total Per Capita Cost
	Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQM)	No	No	
	Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy (Collection Type: MIPS CQM)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
	Q507: Appropriate Germline Testing for Ovarian Cancer Patients (Collection Type: MIPS CQM)	No	No	
	(*) PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy (Collection Type: QCDR)	No	Yes	
	PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure) (Collection Type: QCDR)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost
Radiation Oncology	**Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_PC_1:** Prostate Cancer **(*) TPCC_1:** Total Per Capita Cost
	(*) Q143: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM, MIPS CQM)	No	Yes	

Advancing Cancer Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	(*) Q144: Oncology: Medical and Radiation - Plan of Care for Pain (Collection Type: MIPS CQM)	No	Yes	
Advancing Health and Wellness	**(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_PC_1:** Prostate Cancer **(*) TPCC_1:** Total Per Capita Cost
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_PC_1:** Prostate Cancer **(*) TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPs Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	
	(*) Q453: Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQM)	No	Yes	
	(*) Q457: Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQM)	Yes	Yes	
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Advancing Cancer Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_24:** Financial Navigation Program
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

The following is a summary of the comments we received and our responses.

Comment: A few commenters noted support for the proposed addition of PIMSH15: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents — Avoidance of Overuse and PIMSH16: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents, to this MVP. Another commenter expressed

continued support for the inclusion of Q450: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer, Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy, Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy, Q507: Appropriate Germline Testing for Ovarian Cancer Patients, and PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing the *Advancing Cancer Care MVP* with modifications to Table B.2. for the CY 2026 performance period/2028 MIPS payment year and future years. Based on planned QCDR measure changes, we are not finalizing the addition of PIMSH15: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents in the Infusion Center - Avoidance of Overuse (Lower Score - Better) or PIMSH16: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents in the Infusion Center. Upon completion of the measure changes, we may consider the addition of these measures in future rulemaking.

B.3: Advancing Care for Heart Disease MVP

The B.3 table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Care for Heart Disease MVP (89 FR 99015 through 99019) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Advancing Care for Heart Disease MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, heart disease. This MVP would be most applicable to clinicians who treat patients within the practice cardiology, internal medicine and family medicine, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.3 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[663], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[664], we removed three improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

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[663] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[664] Ibid.

TABLE B.3: Advancing Care for Heart Disease MVP Clinical Groupings

Advancing Care for Heart Disease MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Congestive Heart Failure	**Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	No	No	
	Q377: Functional Status Assessments for Heart Failure (Collection Type: eCQM)	No	Yes	
	Q492: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims)	Yes	Yes	
General Cardiology	**Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **(*) TPCC_1:** Total Per Capita Cost
	Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM, MIPS CQM)	No	No	
	Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQM)	No	No	
	Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQM)	No	Yes	
	Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	Yes	Yes	**(*) TPCC_1:** Total Per Capita Cost
Electrophysiology	**Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQM)	Yes	Yes	**COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient

Advancing Care for Heart Disease MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
				(IP) Percutaneous Coronary Intervention (PCI) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **(*) TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	No	Yes	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **(*) TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

<u>Advancing Care for Heart Disease Improvement Activities</u>

- **(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter supported updates to this MVP but urged additional improvements. The commenter raised concerns about the potential of double-counting performance on related services, called for inclusion of stronger outcome measures in the Electrophysiology and General Cardiology clinical groupings, and suggested modernizing measure sets to reflect current treatment strategies. The commenter advised limiting broad preventive measures in the Health and Wellness clinical grouping for broader MVPs or as optional measures if retained in this MVP. In addition, the commenter believes key gaps remain in this MVP, including measures for hypertension, peripheral artery disease, valvular heart disease, and cardiomyopathies.

Response: We thank the commenter for their support. The new clinical grouping format offers a streamlined set of quality measures to aid clinicians in selecting the most clinically relevant measures applicable to their clinical area and identifies when quality and cost measures are linked but is not intended to represent requirements and may not align with every clinician's scope of care. Currently, reporting of MVPs is voluntary to allow for the flexibility of reporting via traditional MIPS in the instance an MVP does not fit a clinician's scope of care. However, we would encourage the submission of meaningful new measures to the Annual Call for Measures for potential inclusion in future rulemaking. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Care for Heart Disease MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.4: Advancing Rheumatology Patient Care MVP

The B.4 table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Rheumatology Patient Care MVP (89 FR 99019 through 99023) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Advancing Rheumatology Patient Care MVP focuses on the clinical theme of providing fundamental treatment and management of rheumatological conditions. This MVP would be most applicable to clinicians who treat patients within the practice rheumatology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.4 and the list of improvement activities.

Quality Measures

We proposed adding two QCDR measures:

- **ACR10**: Hepatitis B Safety Screening: This QCDR measure improves patient safety by ensuring that a hepatitis B screening is documented in the medical record for all patients newly initiating a biologic or new synthetic immunosuppressive drug.
- **ACR16**: Rheumatoid Arthritis Patients with Low Disease Activity or Remission: This QCDR measure assesses clinician performance based on the risk-adjusted proportion of patients with rheumatoid arthritis who have low disease activity or are in remission based on the last recorded disease activity score as assessed using an ACR-preferred tool.

For the reasons stated in the introduction of this appendix[665], we proposed removing **Q487**: Screening for Social Drivers of Health. We also proposed removing one QCDR measure as this measure was proposed for removal from MIPS:

- **UREQA2**: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy

Modifications are being considered for the following QCDR measure[666]:

- **ACR12**: Disease Activity Measurement for Patients with PsA: This QCDR measure is undergoing modifications to modify the denominator adding telehealth as denominator eligible.

Improvement Activities

For the reasons stated in the introduction of this appendix[667], we removed one improvement activity from this MVP: **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.4: Advancing Rheumatology Patient Care MVP Clinical Groupings

Advancing Rheumatology Patient Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Rheumatoid Arthritis	**Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQM)	No	No	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost
	Q178: Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQM)	No	No	
	Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQM)	No	No	

[665] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[666] Ibid.
[667] Ibid.

Advancing Rheumatology Patient Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Autoimmune/ Inflammatory Diseases	**(*) ACR12:** Disease Activity Measurement for Patients with PsA (Collection Type: QCDR)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	ACR14: Gout: Serum Urate Target (Collection Type: QCDR)	Yes	Yes	
	ACR15: Safe Hydroxychloroquine Dosing (Collection Type: QCDR)	No	Yes	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost
	UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	Yes	Yes	**(*) TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	(*) Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	No	No	
	(+) ACR10: Hepatitis B Safety Screening (Collection Type: QCDR)	No	Yes	
	UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older (Collection Type: QCDR)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
Experience of Care	**(*) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	**COST_RA_1:** Rheumatoid Arthritis **(*) TPCC_1:** Total Per Capita Cost

Advancing Rheumatology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_2:** Tobacco use
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

The following is a summary of the comments we received and our responses.

Comment: A commenter opposed the inclusion of COST_RA_1: Rheumatoid Arthritis in this MVP. The commenter believes this cost measure penalizes physicians for drug costs outside their control and offers little value for improving care. They stated that barriers such as step therapy, the SAD Exclusion List, restrictive formularies, non-medical switching, and inadequate biosimilar reimbursement must be addressed.

Response: We may consider the removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Rheumatology MVP* with modifications in Table B.4 for the CY 2026 performance period/2028 MIPS payment year and future years. We are not finalizing the addition of ACR16: Rheumatoid Arthritis Patients with Low Disease Activity or Remission as the measure didn't meet the criteria for inclusion in MIPS as there was no evidence of a gap in care, outlined within the CY 2021 Medicare PFS Final Rule [§ 414.1400(b)(4)(iv)(G)].

B.5 Complete Ophthalmologic Care MVP

The B.5 table, followed by a list of improvement activities, represents the measures and activities finalized within the Complete Ophthalmologic Care MVP (89 FR 98974 through 98979) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. This MVP would be most applicable to clinicians who treat patients within the practice of ophthalmology and optometry, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.5 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[668], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.
Modifications are being considered for the following QCDR measures[669]:

- **IRIS2**: Glaucoma – Intraocular Pressure Reduction: This QCDR measure is undergoing modifications to revise the denominator by removing the requirement for "documentation of the severity of their glaucoma" to determine denominator eligibility.
- **IRIS13**: Diabetic Macular Edema - Loss of Visual Acuity: This QCDR measure is undergoing modifications to revise the denominator by removing the requirement for "2 visual acuity values with at least one on or after date of treatment" to determine denominator eligibility.

Improvement Activities

For the reasons stated in the introduction of this appendix[670], we removed two improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

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[668] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[669] Ibid.
[670] Ibid.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.5: Complete Ophthalmologic Care MVP Clinical Groupings

Complete Ophthalmologic Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Cataract	**(*) Q191:** Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (Collection Type: eCQM, MIPS CQM)	Yes	Yes	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	No	Yes	
	(*) Q389: Cataract Surgery: Difference Between Planned and Final Refraction (Collection Type: MIPS CQM)	Yes	Yes	
	IRIS54: Complications After Cataract Surgery (Collection Type: QCDR)	Yes	Yes	
	IRIS61: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery (Collection Type: QCDR)	Yes	Yes	
General Ophthalmology	**(*) Q117:** Diabetes: Eye Exam (Collection Type: eCQM, MIPS CQM)	No	No	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	Yes	
Retinal Disease	**Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM)	No	Yes	N/A
	Q384: Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q499: Appropriate screening and plan of care for elevated intraocular pressure following intravitreal or periocular steroid therapy (Collection Type: MIPS CQM)	No	No	
	(*) Q500: Acute posterior vitreous detachment appropriate examination and follow-up (Collection Type: MIPS CQM)	No	No	

Complete Ophthalmologic Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	(*) Q501: Acute posterior vitreous detachment and acute vitreous hemorrhage appropriate examination and follow-up (Collection Type: MIPS CQM)	No	No	
	(*) IRIS13: Diabetic Macular Edema - Loss of Visual Acuity (Collection Type: QCDR)	Yes	Yes	
	IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR)	Yes	Yes	
Glaucoma	**(*) Q012:** Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Collection Type: eCQM)	No	No	N/A
	(*) Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care (Collection Type: Medicare Part B Claims, MIPS CQM)	Yes	Yes	
	(*) IRIS2: Glaucoma – Intraocular Pressure Reduction (Collection Type: QCDR)	Yes	Yes	
	IRIS39: Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure (Collection Type: QCDR)	Yes	Yes	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
Experience of Care	**(*) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation

Complete Ophthalmologic Care Improvement Activities

- **(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_25:** Drug Cost Transparency
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_10:** Care transition documentation practice improvements
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter appreciated the inclusion of clinical subgroupings in this MVP, but believes other subspecialties were omitted, limiting participation. The commenter recommended the inclusion of IRIS1: Endothelial Keratoplasty - Post-operative improvement in best corrected visual acuity to 20/40 or better, IRIS17: Acute Anterior Uveitis - Post-treatment Grade 0 anterior chamber cells, IRIS23: Refractive Surgery - Patients with a postoperative improvement in uncorrected visual acuity (UCVA) of 20/20 or better within 30 days, IRIS35: Improvement of Macular Edema in Patients with Uveitis, IRIS38: Endothelial Keratoplasty - Dislocation Requiring Surgical Intervention, IRIS50: Amblyopia - Interocular visual acuity, IRIS59: Regaining Vision After Cataract Surgery, and IRIS63: Exudative Age-Related Macular Degeneration - Gain of Visual Acuity. The commenter believes that including these additional QCDR measures would enable more ophthalmologists to report outcomes-based measures that better reflect their patients and care quality, allowing for meaningful participation from subspecialties like cornea and uveitis. The measures have been fully developed, tested, and are supported by an adoption plan, which the commenter believes would enhance subspecialist participation. The commenter also recommended the removal of Q303: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery and Q304: Cataracts - Patient Satisfaction within 90 Days Following Cataract Surgery. The commenter believes that reporting on 75 percent of eligible patients is impractical, especially for high-volume procedures like cataract surgery, due to the burden of administering surveys. They recommend using QCDR measures like IRIS59: Regaining Vision After Cataract Surgery to better capture meaningful and achievable outcomes.

Response: We thank the commenter for their support of the addition of clinical groupings. We may consider the inclusion of additional quality measures as well as the removal of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Please note that both measures Q303 and Q304 include denominator exceptions, as we acknowledge the difficulty in receiving completed surveys, therefore, patients that fall into the denominator exception would be counted towards the 75 percent threshold for data completeness.

Comment: A few commenters continue to have concerns with this MVP. The commenters believe the MVP provides inadequate subspecialty representation and as a single, all-encompassing MVP it does not meet the varied needs of the profession. The commenters are also concerned that the single cost measure included in the MVP only applies to cataract surgeons which they believe creates inequity among subspecialists. The commenters do not believe this MVP is functional or fair for ophthalmology and recommend creation of subspecialty-specific MVPs, like a Cataract MVP or include meaningful and equitable measures for all ophthalmic subspecialists. Furthermore, the cost performance category will be reweighted if there is no applicable cost measure. As of the 2024 performance period, the cost scoring policies were updated so that more clinicians are scored at or above the equivalent to the MIPS performance threshold (that is, 7.5 or more achievement points out of 10).

Response: We appreciate the commenters' concerns. The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Development of subspecialty MVPs is based upon several factors, including program goals, measure structure and feasibility, inventory, and interested party feedback. We understand that not all measures are applicable to all clinicians who would choose to report this MVP; however, reporting MVPs is voluntary at this time.

After consideration of public comments, we are finalizing the *Complete Ophthalmologic Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.6: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

The B.6 table, followed by a list of improvement activities, represents the measures and activities finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP (89 FR 99023 through 99025) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP focuses on the clinical theme of providing fundamental prevention and treatment of those patients at risk for or that have had a stroke. This MVP would be most applicable to clinicians who treat patients within the practice of neurology, neurosurgical, and vascular surgery, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which

measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.6 and the list of improvement activities.

Quality Measures
For the reasons stated in the introduction of this appendix[671], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities
For the reasons stated in the introduction of this appendix[672], we removed three improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

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[671] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[672] Ibid.

TABLE B.6: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Clinical Groupings

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Stroke Prevention	**Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQM)	No	No	
	Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	Yes	No	
	Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	No	No	
	(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	Yes	Yes	
Stroke Care	**Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQM)	No	No	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q413: Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	Yes	Yes	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes Improvement Activities

- **(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **IA_BMH_l5:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_l5:** Implementation of episodic care management practice improvements

There were no comments received about the proposed modifications to this MVP. We are finalizing the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.7: Dermatological Care MVP

The B.7 table, followed by a list of improvement activities, represents the measures and activities finalized within the Dermatological MVP (89 FR 98979 through 98984) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Dermatological

Care MVP focuses on the clinical theme of providing treatment and management of dermatologic care. This MVP would be most applicable to clinicians who treat patients within the practice of dermatology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.7 and the list of improvement activities.

Quality Measures

We proposed adding two MIPS quality measures:

- **Q047**: Advance Care Plan: This MIPS quality measure provides a meaningful assessment for patients undergoing dermatological care.
- **Q238:** Use of High-Risk Medications in Older Adults: This MIPS quality measure supports patient safety by assessing for the use of high-risk medications.

For the reasons stated in the introduction of this appendix[673], we proposed removing **Q487**: Screening for Social Drivers of Health. We also proposed removing one MIPS quality measure and two QCDR measures.

- **Q130:** Documentation of Current Medications in the Medical Record.
- **AAD17**: Continuation of Anticoagulation Therapy in the Office-based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures.
- **AAD18**: Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection.

Improvement Activities

For the reasons stated in the introduction of this appendix[674], we removed one improvement activity from this MVP: **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.7: Dermatological Care MVP Clinical Groupings

Dermatological Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Skin Cancer	**Q397:** Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_MR_1:** Melanoma Resection

[673] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[674] Ibid.

Dermatological Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	No	Yes	
	Q509: Melanoma: Tracking and Evaluation of Recurrence (Collection Type: MIPS CQM)	No	No	
	AAD6: Skin Cancer: Biopsy Reporting Time – Clinician to Patient (Collection Type: QCDR)	No	Yes	
	AAD12: Melanoma**:** – Appropriate Surgical Margins (Collection Type: QCDR)	Yes	Yes	
	AAD16: Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures (Collection Type: QCDR)	No	Yes	
Inflammatory Conditions	**(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	No	Yes	N/A
	Q486: Dermatitis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	Yes	Yes	
	Q410: Psoriasis: Clinical Response to Systemic Medications (Collection Type: MIPS CQM)	Yes	Yes	
	Q485: Psoriasis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	Yes	Yes	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_MR_1:** Melanoma Resection
Experience of Care	**(+) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_MR_1:** Melanoma Resection
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	
	AAD8: Chronic Skin Conditions: Patient Reported Quality-of-Life (Collection Type: QCDR)	No	Yes	N/A
Advancing Health and Wellness	**(+) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM))	No	Yes	N/A

Dermatological Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(*)(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements

- **IA_PSPA_8:** Use of Patient Safety Tools

The following is a summary of the comments we received and our responses.

Comment: A commenter noted support for the clinical groupings in this MVP. A couple commenters supported the inclusion of Q47: Advance Care Plan and Q238: Use of High-Risk Medications in Older Adults in this MVP, with a commenter believing these additions would address the lack of measures for general dermatologists and provide greater flexibility for participation regardless of EHR or MIPS registry. A commenter recommended including all measures from the dermatology specialty set to reduce confusion and expand reporting options, specifically the addition of Q374: Closing the Referral Loop: Receipt of Specialist Report and Q317: Screening for High Blood Pressure. The commenter felt their exclusion was arbitrary and raised concerns about the consistency of the measure selection process. A commenter noted support for the clinical groupings in this MVP. The commenter raised concerns about the MVP's separation of cost and quality measures across different conditions, stating it undermines value-based care. They believe cost and quality should be assessed together for the same condition. Specifically, they stated that only clinicians reporting on melanoma quality measures (for example, Q397) should be evaluated on the Melanoma Resection cost measure. Conversely, those reporting on unrelated conditions like inflammatory diseases (for example, Q486) should not be held accountable for melanoma-related costs, especially when no associated cost measure exists for their reported quality measures. Another commenter opposed removing Q130: Documentation of Current Medications in the Medical Record, AAD17: Continuation of Anticoagulation Therapy in the Office-Based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures, and AAD18: Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection because they believe these measures are vital for patient safety and safe prescribing practices, particularly in dermatologic surgery.

Response: We thank the commenters for their support. We appreciate the feedback regarding the clinical groupings and will work to ensure that the purpose is understood. The addition of clinical groupings was at the request of multiple interested parties to further streamline measure selection; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. We may consider the inclusion of additional quality measures or the removal of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

While we agree the concepts are important to quality care, the removal of Q130: Documentation of Current Medications in the Medical Record, AAD17: Continuation of Anticoagulation Therapy in the Office-Based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures, and AAD18: Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection does not preclude the quality actions from continuing. Additionally, QCDR measures must meet the inclusion criteria to be finalized within MIPS and within an MVP. Based upon review of AAD17 and AAD18, they no longer meet that inclusion criteria.

Comment: A commenter believes this MVP is poorly designed, that many measures apply to dermatopathologists rather than dermatologists, and half are only available through a QCDR. The commenter opposed the removal of Q487: Screening for Social Drivers of Health and believed its inclusion would ensure clinical dermatology providers have at least one measure to report. Another commenter urged CMS to not remove any quality measures from this MVP as they believe the MVP already has a limited number of measures and insufficient measures for dermatological subspecialties. They believe if MVPs become the only reporting option available in the future, these clinicians are likely to face penalties through no fault of their own.

Response: We appreciate the commenter's concerns. The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care, such as dermatopathology. We understand that not all measures are applicable to all clinicians who would choose to report this MVP; however, reporting MVPs is voluntary at this time. While four of the quality measures are QCDR measures, there remain nine dermatology related MIPS quality measures, four of which are broadly applicable. We would also note that we are adding measure Q047 to the MVP, which is a cross-cutting quality measure.

After consideration of public comments, we are finalizing the *Dermatological Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.8: Focusing on Women's Health MVP

The B.8 table, followed by a list of improvement activities, represents the measures and activities finalized within the Women's Health MVP (89 FR 99025 through 99029) with modifications for

the CY 2026 performance period/2028 MIPS payment year and future years. The Focusing on Women's Health MVP focuses on the clinical specialty of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practice of gynecology, obstetrics, and urogynecology, including nonphysician practitioners (NPPs) such as certified nurse-midwives, nurse practitioners, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.8 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[675], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[676], we removed four improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_PM_6**: Use of toolsets or other resources to close healthcare disparities across communities, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.8: Focusing on Women's Health MVP Clinical Groupings

Focusing on Women's Health MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Obstetrics	**Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q336: Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	Q496: Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that	No	No	**(*) TPCC_1:** Total Per Capita Cost

[675] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[676] Ibid.

Focusing on Women's Health MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQM)			
Gynecology	**Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQM)	Yes	Yes	
	Q448: Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQM)	No	Yes	
Advancing Health and Wellness	**Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **(*) TPCC_1:** Total Per Capita Cost
	Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	No	No	
	(*)(**) Q112: Breast Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q309: Cervical Cancer Screening (Collection Type: eCQM)	No	No	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	No	No	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	No	No	
	Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM)	No	No	
	Q475: HIV Screening (Collection Type: eCQM)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
	UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia	Yes	Yes	

Focusing on Women's Health MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level (Collection Type: QCDR)			

Focusing on Women's Health Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- **(!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **(!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines

There were no comments received about the proposed modifications to this MVP. We are finalizing the *Focusing on Women's Health MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.9: Gastroenterology Care MVP

The B.9 table, followed by a list of improvement activities, represents the measures and activities finalized within the Gastroenterology Care MVP (89 FR 98984 through 98989) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Gastroenterology Care MVP focuses on the clinical theme of providing treatment and management of the digestive system and the liver. This MVP would be most applicable to clinicians who treat patients within the practice of gastroenterology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.9 and the list of improvement activities.

Quality Measures

We proposed adding one new MIPS quality measure:

- **Q516: Hepatitis C Virus (HCV)**: Sustained Virological Response (SVR)**:** This proposed MIPS quality measure captures an important outcome for this patient population.

For the reasons stated in the introduction of this appendix[677], we proposed removing two MIPS quality measures: **Q185**: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use and **Q487**: Screening for Social Drivers of Health. Modifications are being considered for the following QCDR measures[678]:

- **GIQIC26**: Screening Colonoscopy Adenoma Detection Rate: This QCDR measure is undergoing modifications to update the denominator exclusions to reflect any non-colonoscopy colorectal cancer screening test.

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[677] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[678] Ibid.

- **NHCR4**: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation: This QCDR measure is undergoing modifications to update the numerator to reflect numerator compliance for the clinical scenario of a patient referred for polyp or mass removal.

Improvement Activities

For the reasons stated in the introduction of this appendix[679], we removed two improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Cost Measures

We proposed adding one MIPS cost measure:

- **COST_LGH_1**: Lower Gastrointestinal Hemorrhage: This MIPS episode-based cost measure assesses costs associated with inpatient non-surgical treatment for acute bleeding in the lower gastrointestinal tract.

Symbol Key:

Caret symbol (^): new MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.9: Gastroenterology MVP Clinical Groupings

Gastroenterology Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Interventional / Endoscopy	**(*) GIQIC26:** Screening Colonoscopy Adenoma Detection Rate (Collection Type: QCDR)	Yes	Yes	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost
	N/A	N/A	N/A	**(+) COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Hepatobiliary	**Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	No	No	
	(^)(+) Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM)	Yes	Yes	

[679] Ibid.

Gastroenterology Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Inflammatory	**Q275**: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (Collection Type: MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
General Gastroenterology	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	No	No	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost **(+) COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Advancing Health and Wellness	**(*)(**) Q113:** Colorectal Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost **(+) COST_LGH_1:** Lower Gastrointestinal Hemorrhage
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	
	GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy (Collection Type: QCDR)	No	Yes	
	(*) NHCR4: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation (Collection Type: QCDR)	No	Yes	
Experience of Care	**(*) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	**COST_SSC_1:** Screening/Surveillance Colonoscopy **(*) TPCC_1:** Total Per Capita Cost

Gastroenterology Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_10:** Care transition documentation practice improvements
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(*)(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians

- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

The following is a summary of the comments we received and our responses.

Comment: A commenter questioned the correlation between the cost and quality measures in some of the clinical groupings in this MVP. For example, the commenter would like to understand why COST_SSC_1: Screening/Surveillance Colonoscopy and COST_LGH_1: Lower Gastrointestinal Hemorrhage are included in both the General Gastroenterology and the Advancing Health and Wellness grouping. In addition, the commenter would like to understand why TPCC_1: Total Per Capita Cost is included in the Interventional/Endoscopy grouping when there are two relevant GI cost measures already included in that grouping.

Response: We believe that the Lower Gastrointestinal Hemorrhage cost measure is appropriate to add to this MVP. The Lower Gastrointestinal cost measure assesses costs associated with inpatient non-surgical treatment for acute bleeding in the lower gastrointestinal tract and is often attributed to gastroenterologists. We continue to believe that the Screening/Surveillance Colonoscopy and Total Per Capita Cost (TPCC) cost measures are appropriate for use in this MVP for the reasons noted in the CY 2025 PFS final rule (89 FR 98986 through 98989). While the TPCC cost measure can capture cost savings associated with appropriate use of colonoscopies, we agree that the TPCC cost measure may not be as applicable to interventional/endoscopy gastroenterology and will consider removing it from that clinical grouping. The purpose of the clinical groupings is to streamline quality measure selection and identify links between cost and quality measures; however, these clinical groupings do not represent requirements and may not align with every clinician's scope of care. Clinicians and groups who choose to report the Gastroenterology MVP may be scored on the TPCC cost measure if they meet the established case minimum. Clinicians and groups who do not meet the established case minimum will not be scored on the cost measure.

Comment: A commenter appreciated the more user-friendly format but believes the clinical groupings in this MVP highlight the gaps in the availability of meaningful quality measures specific and important to gastroenterologists. The commenter believes that quality measures added to this MVP are more applicable to primary care providers and are not meaningful to gastroenterologist.

Response: We acknowledge the commenters' concerns and encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years. We understand that not all measures are applicable to all clinicians who would choose to report this MVP; however, reporting MVPs is voluntary at this time. We encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years.

After consideration of public comments, we are finalizing the *Gastroenterology Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.10: Improving Care for Lower Extremity Joint Repair MVP

The B.10 table, followed by a list of improvement activities, represents the measures and activities finalized within the Improving Care for Lower Extremity Joint Repair MVP (89 FR 99029 through 99031) with modifications for the CY 2026 performance period/2028 MIPS payment year and future years. The Improving Care for Lower Extremity Joint Repair MVP focuses on the clinical theme of providing fundamental treatment and management of patients with osteoarthritis and lower extremity surgical repair, such as fracture and total joint replacement, to ensure appropriate care and reduce costs. This MVP would be most applicable to clinicians who treat patients within the practice of orthopedic surgery, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.10 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[680], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[681], we removed two improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

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[680] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[681] Ibid.

TABLE B.10: Improving Care for Lower Extremity Joint Repair MVP Clinical Groupings

Improving Care for Lower Extremity Joint Repair MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Non-Surgical	**Q024:** Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
Surgical	**Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQM)	No	Yes	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
	Q351: Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQM)	No	Yes	
	(*) Q376: Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM)	No	Yes	**COST_PHA_1:** Elective Primary Hip Arthroplasty
	Q470: Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQM)	Yes	Yes	**COST_KA_1:** Knee Arthroplasty
	(*) Q480: Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims)	Yes	Yes	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty

Improving Care for Lower Extremity Joint Repair Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles
- **IA_CC_15:** PSH Care Coordination
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level

There were no comments received about the proposed modifications to this MVP. We are finalizing the *Improving Care for Lower Extremity Joint Repair MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.11: Optimal Care for Kidney Health MVP

The B.11 table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Kidney Health MVP (89 FR 99031 through 99035) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Optimal Care for Kidney Health MVP focuses on the clinical specialty of

providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. This MVP would be most applicable to clinicians who treat patients within the practice of nephrology. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.11 and the list of improvement activities.

Quality Measures

We proposed adding one new MIPS quality measure:

- **Q512: Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)**: This proposed MIPS quality measure captures an additional population of patients on transplant list beyond their first year of dialysis.

For the reasons stated in the introduction of this appendix[682], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[683], we removed three improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Caret symbol (^): new MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.11: Optimal Care for Kidney Health MVP Clinical Groupings

Optimal Care for Kidney Health MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
General Nephrology	**Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease
	Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	

[682] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[683] Ibid.

Optimal Care for Kidney Health MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
				COST_KTM_1: Kidney Transplant Management **(*) TPCC_1:** Total Per Capita Cost
	(*) Q488: Kidney Health Evaluation (Collection Type: eCQM, MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM)	No	No	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **(*) TPCC_1:** Total Per Capita Cost
Dialysis/Transplant	**Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQM)	Yes	Yes	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **(*) TPCC_1:** Total Per Capita Cost
	Q510: First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQM)	Yes	No	**COST_ESRD_1:** End-Stage Renal Disease **(*) TPCC_1:** Total Per Capita Cost
	Q511: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Collection Type: MIPS CQM)	Yes	No	
	(^)(+) Q512: Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR) (Collection Type: MIPS CQM)	No	No	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **(*) TPCC_1:** Total Per Capita Cost
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
	Q047: Advance Care Plan	No	Yes	

Optimal Care for Kidney Health MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Experience of care	(Collection Type: Medicare Part B Claims, MIPS CQM)			**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **(*) TPCC_1:** Total Per Capita Cost
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	Yes	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Optimal Care for Kidney Health Improvement Activities

- **(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(!) IA_BE_16**: Promote Self-management in Usual Care
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13**: Practice Improvements to Align with OpenNotes Principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs

The following is a summary of the comments we received and our responses.

Comment: A commenter noted support for the Dialysis/Transplant clinical grouping in this MVP.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing the *Optimal Care for Kidney Health MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.12: Optimal Care for Patients with Urologic Conditions MVP

The B.12 table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Urologic Conditions MVP (89 FR 98989 through 98994) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Optimal Care for Patients with Urologic Conditions MVP focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence, bladder cancer, and prostate cancer. This MVP would be most applicable to clinicians who treat patients within the practices of urology, general urologists, urology oncologists, and urology care for women, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to

determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.12 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[684], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[685], we removed three improvement activities from this MVP: **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B, and **IA_PSPA_19**: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.12: Optimal Care for Patients with Urologic Conditions MVP Clinical Groupings

Optimal Care for Patients with Urologic Conditions MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Urological Cancer	**Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	No	No	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q476: Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia (Collection Type: eCQM)	Yes	Yes	
	Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer (Collection Type: eCQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	AQUA8: Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy (Collection Type: QCDR)	Yes	Yes	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	AQUA16: Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 disease (Collection Type: QCDR)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients	No	Yes	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending

[684] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[685] Ibid.

Optimal Care for Patients with Urologic Conditions MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	(Collection Type: QCDR)			Per Beneficiary (MSPB) Clinician
General Urology	**Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	No	Yes	**COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	AQUA14: Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment (Collection Type: QCDR)	Yes	Yes	
	AQUA15: Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures (Collection Type: QCDR)	No	Yes	
Advancing Health and Wellness	**Q318:** Falls: Screening for Future Fall Risk (Collection Type: eCQM)	No	Yes	**COST_PC_1:** Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	**COST_PC_1:** Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Optimal Care for Patients with Urologic Conditions Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7**: Regular training in care coordination
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

The following is a summary of the comments we received and our responses.

Comment: A commenter agreed with the removal of IA_PM_26: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B from this MVP.

Response: We thank the commenter for their support.

Comment: A commenter believes this MVP is mainly suited for large organizations that can integrate with systems like the AQUA registry. The commenter noted the MVP lacks claims-based measures and eCQMs, tools widely supported by EHRs and crucial for enabling smaller practices to participate. The commenter recommended relevant claims-based options be added to make this MVP more accessible to a broader range of practices.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, this is not currently a requirement, and not all measures are submitted to the Annual Call for Quality Measures with an option for the eCQM collection type. We strive to include measures from different collection types to allow flexibility in reporting but are limited to the collection types developed and submitted by the measure steward. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs or claims-based to discuss revisions for possible implementation in futures years.

Comment: A commenter disagreed with the removal of IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes. The commenter believes this improvement activity is warranted as it allows for significant flexibility in the focus area of the quality improvement completed.

Response: We appreciate commenter's feedback. IA_PSPA_19 has been removed from all MVPs as IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways is substantially similar.

After consideration of public comments, we are finalizing the *Optimal Care for Patients with Urologic Conditions MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.13: Patient Safety and Support of Positive Experiences with Anesthesia MVP

The B.13 table, followed by a list of improvement activities, represents the measures and activities finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP (89 FR 99035 through 99037) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Patient Safety and Support of Positive Experiences with Anesthesia MVP focuses on increasing the quality of anesthesia care, improving postoperative outcomes, promoting patient safety, and enhancing satisfaction for patients receiving anesthesia. The measures are used for a variety of surgical procedures that anesthesiologists deliver care for, and are broadly applicable to anesthesiologists practicing within ambulatory, outpatient, and inpatient hospital settings, including NPPs such as certified registered nurse anesthetists (CRNAs) and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.13 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[686], we proposed removing two MIPS quality measures: **Q424**: Perioperative Temperature Management and **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[687], we removed two improvement activities from this MVP: **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.

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[686] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

[687] Ibid.

Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.13: Patient Safety and Support of Positive Experiences with Anesthesia MVP Clinical Groupings

Patient Safety and Support of Positive Experiences with Anesthesia MVP				
Condition	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Sedation/General Anesthesia	**Q404:** Anesthesiology Smoking Abstinence (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q430: Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQM)	No	Yes	
	Q463: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQM)	No	Yes	
	ABG44: Low Flow Inhalational General Anesthesia (Collection Type: QCDR)	No	Yes	
	EPREOP31: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	Yes	Yes	
Pain Management	**Q477**: Multimodal Pain Management (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Patient Safety and Support of Positive Experiences with Anesthesia Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_22:** Improved practices that engage patients pre-visit
- **(!) IA_BMH_2:** Tobacco use
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs

The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended adding EPREOP30: Ultrasound Guidance for Peripheral Nerve Block with Patient Experience and including more general measures such as Q130: Documentation of Current Medications in the Medical Record to this MVP to increase relevance for all anesthesia providers.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter noted appreciation for efforts to improve this MVP but urges the replacement of the topped-out Q424: Perioperative Temperature Management measure with another relevant process or outcome measure. The commenter noted that the current anesthesia measure set is limited, which may hinder providers, especially in multispecialty groups, from demonstrating quality improvement. The commenter recommended adding

patient-centered measures, such as postoperative pain levels or the Bauer Patient Satisfaction Questionnaire, to enhance the MVP's value and better capture patient experience and outcomes. A couple of commenters opposed the removal of Q424: Perioperative Temperature Management from this MVP as they believe this measure is an essential anesthesiologist measure, representing a critical clinical workflow preserving patient safety and the prevention of adverse events such as postoperative infections.

Response: We thank the commenter for their support. We acknowledge the commenter's concern regarding removing measures without replacements; however, we also endeavor to balance meaningful reporting with burden. While topped-out measures represent an important aspect of care, the quality action is considered a standard of care with limited opportunity to improve clinical outcomes. Removal allows eligible clinicians to maximize their potential quality performance score as these measures topped out status would likely limit the score awarded. We encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years. Additionally, we would encourage the commenter to reach out to the measure stewards of patient-centered measures to ensure these measures are appropriate and applicable to anesthesiologists, that is, the denominator criteria including the coding is representative of this specialty, for potential inclusion in future years. We appreciate the commenters' feedback on Q424: Perioperative Temperature Management. This measure has been finalized to be removed from the program and therefore will be removed from this MVP. For the full rationale for the removal of Q424, please review Appendix 1: MIPS Quality Measures of this final rule, Table Group C.

After consideration of public comments, we are finalizing the *Patient Safety and Support of Positive Experiences with Anesthesia MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.14: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

The B.14 table, followed by a list of improvement activities, represents the measures and activities finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP (89 FR 99038 through 99040) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on the clinical specialty of promoting quality care for patients suffering from infectious disorders. This MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.14 and the list of improvement activities.

Quality Measures

We proposed adding one new MIPS quality measure:

- **Q516: Hepatitis C Virus (HCV)**: Sustained Virological Response (SVR)**:** This proposed MIPS quality measure that captures important outcome for this patient population.

For the reasons stated in the introduction of this appendix[688], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[689], we removed four improvement activities from this MVP: **IA_AHE_5**: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_PM_6**: Use of toolsets or other resources to close healthcare disparities

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[688] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[689] Ibid.

across communities, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis.

Cost Measures

We proposed adding three additional MIPS cost measures:

- **COST_RIH_1:** Respiratory Infection Hospitalization: This MIPS episode-based cost measure assesses costs associated with inpatient treatment for a respiratory infection.
- **COST_S_1:** Sepsis: This MIPS episode-based cost measure assesses costs associated with inpatient medical treatment for sepsis.
- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care for acute infections in inpatient hospitals.

Symbol Key:

Caret symbol (^): new MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.14: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Clinical Groupings

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Chronic: Hep C, HIV/AIDS	**Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: eCQM, MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q338: HIV Viral Suppression (Collection Type: eCQM, MIPS CQM)	Yes	Yes	
	Q340: HIV Medical Visit Frequency (Collection Type: MIPS CQM)	No	Yes	
	Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQM)	No	No	
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	No	No	
	(^)(+) Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM	Yes	Yes	
Acute Infection	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI)	No	Yes	**(*) TPCC_1:** Total Per Capita Cost

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	(Collection Type: eCQM, MIPS CQM)			
	N/A			**(+) COST_RIH_1:** Respiratory Infection Hospitalization **(+) COST_S_1:** Sepsis **(+) MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**(+) COST_RIH_1:** Respiratory Infection Hospitalization **(+) COST_S_1:** Sepsis **(+) MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q240: Childhood Immunization Status (Collection Type: eCQM)	No	No	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	No	No	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	No	No	
	Q475: HIV Screening (Collection Type: eCQM)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **(!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship
- **(!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the inclusion of Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR). The commenter believes the use of this measure in performance measurement will incentivize best practices and improved patient outcomes. The commenter also supported the addition of COST_RIH_1: Respiratory Infection Hospitalization, COST_S_1: Sepsis, and MSPB_1: Medicare Spending Per Beneficiary (MSPB) Clinician.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing the *Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.15: Pulmonology Care MVP

The B.15 table, followed by a list of improvement activities, represents the measures and activities finalized within the Pulmonology Care MVP (89 FR 98994 through 98998) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Pulmonology Care MVP focuses on assessing optimal care for patients treated for a broad range of pulmonology conditions including COPD, asthma, sleep apnea, and general pulmonology. This MVP would be most applicable to clinicians who specialize in pulmonology and sleep medicine, including NPPs such as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.15 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[690], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[691], we removed three improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

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[690] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[691] Ibid.

Table B.15: Pulmonology Care MVP Clinical Groupings

Pulmonology Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Asthma	**Q398:** Optimal Asthma Control (Collection Type: MIPS CQM)	Yes	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD)
COPD	**Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy (Collection Type: MIPS CQM)	No	No	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD (Collection Type: QCDR)	No	No	
Sleep Medicine	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	No	No	N/A
	Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy (Collection Type: MIPS CQM)	No	No	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Pulmonology Care Improvement Activities

- **(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_23:** Integration of patient coaching practices between visits
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter recommended adding Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis.

Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Pulmonology Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.16: Quality Care for Patients with Neurological Conditions MVP

The B.16 table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for Patients with Neurological Conditions MVP (89 FR 99040 through 99044) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Quality Care for Patients with Neurological Conditions MVP focuses on the clinical theme of promoting quality care for patients suffering from neurological conditions. This MVP would be most applicable to clinicians who specialize in neurology care, including NPPs such as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.16 and the list of improvement activities.

Quality Measures

We proposed adding one new MIPS quality measure:

- **Q513: Patient reported falls and plan of care**: This proposed MIPS quality measure captures falls assessment and care plan specific to patients with neurological conditions.

For the reasons stated in the introduction of this appendix[692], we proposed removing **Q487:** Screening for Social Drivers of Health. We also proposed removing three additional MIPS quality measures:

- **Q155**: Falls: Plan of Care
- **Q290**: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease
- **Q419**: Overuse of Imaging for the Evaluation of Primary Headache

Improvement Activities

For the reasons stated in the introduction of this appendix[693], we removed three improvement activities from this MVP: **IA_BMH_8**: Electronic Health Record Enhancements for BH data capture, **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Caret symbol (^): new MIPS quality and Promoting Interoperability measures.
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

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[692] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[693] Ibid.

TABLE B.16: Quality Care for Patients with Neurological Conditions MVP Clinical Groupings

Quality Care for Patients with Neurological Conditions MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Brain Conditions	**Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dementia	**(*) Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q282: Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	No	No	
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
	Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	No	Yes	
Neurodegenerative Disorders	**Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	No	No	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician
	Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	No	Yes	
	Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM)	No	Yes	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	No	Yes	
	(^)(+) Q513: Patient reported falls and plan of care (Collection Type: MIPS CQM)	No	Yes	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	Yes	Yes	

Quality Care for Patients with Neurological Conditions MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: MIPS CQM)			
	(*) Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	Yes	Yes	

Quality Care for Patients with Neurological Conditions Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_24:** Financial Navigation Program
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_4:** Depression screening
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_ PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

There were no comments received about the proposed modifications to this MVP. We are finalizing the *Quality Care for Patients with Neurological Conditions MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.17: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

The B.17 table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP (89 FR 99044 through 99047) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on the clinical specialty of providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL) and otitis media. This MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.17 and the list of improvement activities.

Quality Measures

We proposed adding one additional QCDR measure:

- **AA016**: Age-Related Hearing Loss: Audiometric Evaluation: This QCDR measure ensures patients who failed a hearing screening and/or who report suspected hearing loss receive, are ordered, or are referred for a comprehensive audiometric evaluation in a timely fashion.

For the reasons stated in the introduction of this appendix[694], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[695], we removed three improvement activities from this MVP: **IA_AHE_5**: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.17: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Clinical Groupings

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Otology	**AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR)	No	No	N/A
	AAO21: Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR)	No	No	
Sleep Disorders	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	No	No	N/A
General Otolaryngology	**Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	No	Yes	N/A
	Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQM)	No	Yes	
	(+) AAO16: Age-Related Hearing Loss: Audiometric Evaluation	No	Yes	

[694] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[695] Ibid.

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	(Collection Type: QCDR)			
Surgical	**Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	Yes	Yes	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	

Quality Care for the Treatment of Ear, Nose, and Throat Disorders Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter agreed with the reinstatement of AAO16: Age-Related Hearing Loss Audiometric Evaluation and questioned its removal from the MVP. The commenter urges a more collaborative and transparent approach when refining MVPs.

Response: We thank the commenter for their support. We acknowledge the commenter's feedback and will continue to refine workflows as needed to create a collaborative approach for MVP maintenance.

After consideration of public comments, we are finalizing the *Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.18: Quality Care in Mental Health and Substance Use Disorders MVP

The B.18 table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care in Mental Health and Substance Use Disorders MVP (89 FR 99047 through 99049) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Quality Care in Mental Health and Substance Use Disorders MVP focuses on the clinical specialty of promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, and physician assistants. We reviewed the improvement

activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.18 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[696], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[697], we removed five improvement activities from this MVP: **IA_AHE_5**: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR, **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_PM_6**: Use of toolsets or other resources to close healthcare disparities across communities, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.18: Quality Care in Mental Health and Substance Use Disorders MVP Clinical Groupings

Quality Care in Mental Health and Substance Use Disorders MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Mental Health—General	**Q009:** Anti-Depressant Medication Management (Collection Type: eCQM)	No	No	**COST_DEP_1**: Depression
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q366: Follow-Up Care for Children Prescribed ADHD Medication (Collection Type: eCQM)	No	No	N/A
	Q370: Depression Remission at Twelve Months (Collection Type: eCQM, MIPS CQM)	Yes	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions

[696] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[697] Ibid.

Quality Care in Mental Health and Substance Use Disorders MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQM)	Yes	Yes	**COST_PRC_1:** Psychoses/Related Conditions
	MBHR2: Anxiety Response at 6-months (Collection Type: QCDR)	Yes	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	Yes	Yes	N/A
Mental Health—Suicide	**Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM)	No	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQM)	No	Yes	
	Q505: Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQM)	Yes	Yes	
Substance Use Disorder	**Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	No	Yes	N/A
	Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQM)	No	Yes	
Experience of Care	**Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQM)	Yes	Yes	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Mental Health and Substance Use Disorders Improvement Activities

- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_23:** Integration of patient coaching practices between visits
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_2:** Tobacco use
- **(!) IA_BMH_5:** MDD prevention and treatment interventions
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

There were no comments received about the proposed modifications to this MVP. We are finalizing the *Mental Health and Substance Use Disorder* MVP with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.19: Rehabilitative Support for Musculoskeletal Care MVP

The B.19 table, followed by a list of improvement activities, represents the measures and activities finalized within the Rehabilitative Support for Musculoskeletal Care MVP (89 FR 99049 through 99054) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Rehabilitative Support for Musculoskeletal Care MVP focuses on the clinical specialty of promoting quality care for patients. This MVP would be most applicable to clinicians and NPPs who specialize in providing rehabilitative support for musculoskeletal care such as chiropractic, physiatry, physical therapy and occupational therapy, as well as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.19 and the list of improvement activities.

Quality Measures

We proposed adding two additional MIPS quality measures based on maintenance requests and providing meaningful and comprehensive assessment of the clinical care for clinicians providing musculoskeletal care to patients:

- **Q134**: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- **Q182**: Functional Outcome Assessment

For the reasons stated in the introduction of this appendix[698], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Modifications are being considered for the following QCDR measures[699]:

- **MSK6**: Patients Suffering From a Neck Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."
- **MSK7:** Patients Suffering From an Upper Extremity Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."
- **MSK8:** Patients Suffering From a Back Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."
- **MSK9**: Patients Suffering From a Lower Extremity Injury who Improve Pain: This QCDR measure is undergoing modifications to update the denominator exclusions for this QCDR measure to remove "patients that are non-English speaking and translation services are unavailable."

Improvement Activities

We proposed adding three additional improvement activities that address maintenance requests from the public, as well as address the priority area of advancing health and wellness:

- **IA_BE_15**: Engagement of Patients, Family and Caregivers in Developing a Plan of Care

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[698] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update

[699] Ibid.

- **IA_BE_16**: Evidenced-based techniques to promote self-management into usual care
- **IA_AHW_1**: Chronic Care and Preventative Care Management for Empaneled Patients

For the reasons stated in the introduction of this appendix[700], we removed four improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:
Plus sign (+): quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

TABLE B.19: Rehabilitative Support for Musculoskeletal Care MVP Clinical Groupings

Rehabilitative Support for Musculoskeletal Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Orthopedic	**(+) Q182:** Functional Outcome Assessment (Collection Type: MIPS CQM)	No	Yes	**COST_LBP_1:** Low Back Pain
	Q217: Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQM)	Yes	Yes	N/A
	Q218: Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	Q219: Functional Status Change with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	Q220: Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQM)	Yes	Yes	**COST_LBP_1:** Low Back Pain
	Q221: Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQM)	Yes	Yes	N/A
	Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	Q478: Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQM)	Yes	Yes	
	(*) MSK6: Patients Suffering From a Neck Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	

[700] Ibid.

Rehabilitative Support for Musculoskeletal Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
	(*) MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	
	(*) MSK8: Patients Suffering From a Back Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	**COST_LBP_1:** Low Back Pain
	(*) MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain (Collection Type: QCDR)	Yes	Yes	N/A
Geriatric	**Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	No	Yes	N/A
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_LBP_1:** Low Back Pain
	(+)(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	
	Q155: Falls: Plan of Care (Collection Type: MIPS CQM)	No	Yes	

Rehabilitative Support for Musculoskeletal Care Improvement Activities

- **(+)(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(+) IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care
- **(+)(!) IA_BE_16:** Promote Self-management in Usual Care
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(*)(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

The following is a summary of the comments we received and our responses.

Comment: A couple of commenters agreed with the addition of the clinical groupings in this MVP. A commenter believes the groupings will help clinicians select measures relevant to their practice and patient population. A commenter noted support for the proposed quality measure and improvement activity additions to this MVP. The commenter also believes the PROMIS measure set should be reconsidered for inclusion in future iterations of this MVP and recommended the addition of IA_PM_13 and IA_CC_9 as they believe these activities are relevant options for physical therapists. A commenter noted support for the noted modifications to MSK6: Patients Suffering From a Neck Injury who Improve Pain, MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain, MSK8: Patients Suffering From a Back Injury who Improve Pain, and MSK9: Patients Suffering From a Lower Extremity

Injury who Improve Pain. A few commenters recommended the addition of MSK1: Patients Suffering From a Neck Injury who Improve Physical Function, MSK2: Patients Suffering From an Upper Extremity Injury who Improve Physical Function, MSK3: Patients Suffering From a Back Injury who Improve Physical Function, MSK4: Patients Suffering From a Lower Extremity Injury who Improve Physical Function, MSK5: Patients Suffering From a Knee Injury who Improve Physical Function, and MSK10: Patients Suffering From a Knee Injury who Improve Pain. The commenters believe the addition of these measures would allow providers the use of a full suite of patient-reported measures of functional status and pain. In addition, they believe these measures offer components that are interoperable and accessible to health information technology systems. In contrast, the commenters believe the following measures are only available with a subscription or via a highly burdensome public access site and should be removed from the MVP; Q217: Functional Status Change for Patients with Knee Impairments, Q218: Functional Status Change for Patients with Hip Impairments, Q219: Functional Status Change with Lower Leg, Foot or Ankle Impairments, Q220: Functional Status Change for Patients with Low Back Impairments, Q221: Functional Status Change for Patients with Shoulder Impairments, Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments, and Q478: Functional Status Change for Patients with Neck Impairments. In addition, the commenters requested alignment of the process measures in this MVP with the proposed Ambulatory Specialty Model (ASM). The commenters believe this will create a logical and less burdensome future for clinicians. A couple of commenters supported the addition of Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan. A commenter agreed with maintaining Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (BMI). A commenter recommended the removal of Q155: Falls: Plan of Care and does not support the addition of Q182: Functional Outcome Assessment as the measures are topped-out. The commenter also suggested replacing Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older with Q238: Use of High-Risk Medications in Older Adults. A commenter agreed with the inclusion of Q182: Functional Outcome Assessment. A commenter recommended the addition of Q236: Controlling High Blood Pressure to this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures or the removal of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We acknowledge the inclusion of a topped-out measure is not ideal, however, Q182 was added to ensure this important clinical concept is captured in the instance an alternative measure is required as opposed to the more specific functional outcome measures. In addition, including Q182 in this MVP could result in increased reporting of the measure which may impact the benchmark.

Comment: A couple of commenters opposed the removal of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and IA_AHE_12: Practice Improvements to Engage Community Resources to Address Drivers of Health, stating that patients with musculoskeletal conditions often face non-medical barriers such as food insecurity, transportation challenges, and housing instability. These barriers affect their ability to benefit from rehabilitative care, impacting treatment adherence, functional recovery, and long-term health outcomes. The commenter believes that activities promoting screening for these barriers and rewarding providers for engaging with community resources ensure more personalized and effective care. Research indicates that addressing these upstream drivers improves patient engagement, reduces avoidable healthcare utilization, and enhances functional outcomes, especially for older adults and those with complex needs. Removing these activities could overlook significant influences on patient recovery, potentially leading to poorer outcomes, higher costs, and reduced incentives for whole-person care.

Response: We thank the commenters for their feedback. While we acknowledge the importance of practice improvements to engage community resources and focus on nutrition, these specific improvement activities are not fully aligned with the shift in priorities to health, wellness, and prevention. As proper screening and nutrition are fundamental to maintaining health, preventing chronic disease, and supporting resilience; we will consider how we can elevate these topics as part of a broader wellness agenda for possible inclusion in new or current improvement activities in future rulemaking. After consideration of public comments, we are finalizing the removal of the eight improvement activities as proposed.

After consideration of public comments, we are finalizing the *Rehabilitative Support for Musculoskeletal Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.20: Surgical Care MVP

The B.20 table, followed by a list of improvement activities, represents the measures and activities finalized within the Surgical Care MVP (89 FR 98998 through 99005) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Surgical Care MVP focuses on the clinical theme of surgery. This MVP would be most applicable to clinicians who specialize in general surgery, neurosurgery, and cardiothoracic surgery, including NPPs such as nurse practitioners and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.20 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[701], we proposed removing two MIPS quality measures: **Q264**: Sentinel Lymph Node Biopsy for Invasive Breast Cancer and **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[702], we removed two improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols and **IA_PM_26**: Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with an advancing health and wellness component.

B.20: Surgical Care MVP

Surgical Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Cardiothoracic Surgery	**Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Collection Type: MIPS CQM)	Yes	Yes	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure (Collection Type: MIPS CQM)	Yes	Yes	
	Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration (Collection Type: MIPS CQM)	Yes	Yes	
	Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) (Collection Type: MIPS CQM)	Yes	Yes	

[701] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[702] Ibid.

Surgical Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
General Surgery	**Q354:** Anastomotic Leak Intervention (Collection Type: MIPS CQM)	Yes	Yes	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q355: Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	Yes	Yes	**COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	Yes	Yes	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1**: Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Neurosurgical	**Q459:** Back Pain After Lumbar Surgery (Collection Type: MIPS CQM)	Yes	Yes	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q461: Leg Pain After Lumbar Surgery (Collection Type: MIPS CQM)	Yes	Yes	
	Q471: Functional Status After Lumbar Surgery (Collection Type: MIPS CQM)	Yes	Yes	
Advancing Health and Wellness	**Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple

Surgical Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
				Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	No	Yes	

Surgical Care Improvement Activities

- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_18:** Relationship-Centered Communication
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

The following is a summary of the comments we received and our responses.

Comment: A couple commenters expressed concerns about the arbitrary construction of this MVP and even stronger concerns with classifying three spine measures as “neurosurgical," noting that neurosurgery is far broader than spine surgery, and subspecialties like cerebrovascular, brain tumor, functional, neurotrauma, and pediatric care are not reflected in these measures. A commenter believes there is a lack of consistency between the quality and cost measures labeled as "neurosurgical". The commenter believes these disparities will result in inaccurate assessments of value and lead to unfair outcomes. Furthermore, the commenter believes this will create an incentive to delay care, such as physical therapy, until after the acute cost measurement episode has ended. A commenter is concerned with the inclusion of Q355: Unplanned Reoperation and Q357: Surgical Site Infection. The commenter believes these measures are focused almost entirely on general surgery and are not applicable across surgical specialties.

Response: While we acknowledge the commenter's concern, our current measure inventory limits available options, which does not allow for the creation of individual robust, meaningful MVPs for each surgical specialty, or to ensure that all subspecialties are able to meaningfully participate. Clinicians who choose to report this MVP would still report data based upon the measures that are most applicable to their scope of care, allowing for an alternate option to traditional MIPS especially when choosing subgroup reporting with MVPs. We encourage the development of new measures and submission to the Call for Measures for potential inclusion in future years.

Comment: A commenter supported retaining the Lumpectomy, Partial Mastectomy, Simple Mastectomy episode-based cost measure in this MVP, noting it reflects breast surgeons' care and may encourage greater MVP participation.

Response: We thank the comment for their support.

After consideration of public comments, we are finalizing the *Surgical Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

B.21: Value in Primary Care MVP

The B.21 table, followed by a list of improvement activities, represents the measures and activities finalized within the Value in Primary Care MVP (89 FR 99054 through 99057) with modifications for the CY 2025 performance period/2027 MIPS payment year and future years. The Value in Primary Care MVP focuses on the clinical theme of promoting quality care for patients to reduce the risk of diseases, disabilities, and death. This MVP would be most applicable to clinicians who specialize in preventive medicine, internal medicine, family medicine and geriatrics, including NPPs such as nurse practitioners and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses for this MVP are included immediately after Table B.21 and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix[703], we proposed removing one MIPS quality measure: **Q487**: Screening for Social Drivers of Health.

Improvement Activities

For the reasons stated in the introduction of this appendix[704], we removed four improvement activities from this MVP: **IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols, **IA_AHE_12**: Practice Improvements that Engage Community Resources to Address Drivers of Health, **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results, and **IA_PM_26**: Vaccine Achievement for Practices Staff: COVID-19, Influenza, and Hepatitis B.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Single exclamation point (!): improvement activities with advancing health and wellness component.

TABLE B.21: Value in Primary Care MVP Clinical Groupings

[703] See MVP Development: Quality Measure and Improvement Activities Updates and MVP Format Update
[704] Ibid.

Value in Primary Care MVP				
Clinical Grouping	**Quality**			**Cost**
	Measure	**Outcome**	**High Priority**	
Chronic Conditions	**Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_D_1:** Diabetes **(*) TPCC_1:** Total Per Capita Cost
	Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	Yes	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	Q305: Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	No	Yes	N/A
	Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	No	No	**(*) TPCC_1:** Total Per Capita Cost
	Q504: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQM)	No	Yes	**COST_DEP_1:** Depression **(*) TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	No	No	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **(*) TPCC_1:** Total Per Capita Cost
	Q475: HIV Screening (Collection Type: eCQM)	No	No	
	(*) Q493: Adult Immunization Status (Collection Type: MIPS CQM)	No	No	
	Q497: Preventive Care and Wellness (composite) (Collection Type: MIPS CQM)	No	No	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	No	Yes	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor)	No	Yes	
	Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)	Yes	Yes	

Value in Primary Care MVP				
Clinical Grouping	Quality			Cost
	Measure	Outcome	High Priority	
	(Collection Type: MIPS CQM)			**(*) TPCC_1:** Total Per Capita Cost

Value in Primary Care Improvement Activities

- **(*)(!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(*)(!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **(!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **(!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
- **(!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

The following is a summary of the comments we received and our responses.

Comment: A commenter recommended adding Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Value in Primary Care MVP* with modifications as proposed for the CY 2026 performance period/2028 MIPS payment year and future years.

APPENDIX 4: MEASURES FOR MIPS COST PERFORMANCE CATEGORY

We refer readers to section X of this final rule for more information regarding the statutory authority for and existing policies pertaining to the specification of measures for the cost performance category.

Except as otherwise noted in this final rule, previously finalized cost measures will continue to apply for the CY 2026 performance period/2028 MIPS payment year and future years. Previously finalized measures and specialty sets are set forth in Table 75 in the CY 2025 PFS final rule (89 FR 98406).

The Group A Table(s) within this final rule set forth our proposals to modify one or more measures specified for the MIPS cost performance category beginning with the CY 2026 performance period/2028 MIPS payment year.

In the CY 2026 PFS proposed rule (90 FR 33258 through 33261) we proposed modification(s) to the cost measure(s) set forth in the Group A Table(s) consistent with the criteria we established in the CY 2022 PFS final rule for determining whether a proposed change to a cost measure would be substantive (86 FR 65459 and 65460).

Group A: Modify MIPS Cost Measures Beginning with the CY 2026 Performance Period/ 2028 MIPS Payment Year

A.1. Total Per Capita Cost (TPCC)

Category	**Description**
CBE # :	3575
MIPS # :	TPCC_1
Current Measure Description:	TPCC assesses the overall cost of care delivered to a patient with a focus on the primary care they receive from their provider(s). The measure is payment-standardized, risk-adjusted, and specialty-adjusted.
Measure Case Minimum	20 beneficiaries as set forth in § 414.1350(c)(1)
Measure Steward:	Centers for Medicare & Medicaid Services (CMS)
Measure Type:	Population-based cost measure

Category	Description
Substantive Change(s):	**Initiating a candidate event would be modified as follows:** ● Modifications to Measure Specifications for Triggering a Candidate Event: ++ A candidate event will be initiated by two claims for outpatient evaluation and management (E/M) services indicative of primary care. The second service used to initiate a candidate event would have to be another E/M primary care service or another general primary care service from the **same** clinician group (TIN) within 90 days. ++ **Both the first and second service** will have to be provided by a clinician (TIN-NPI) that has not been excluded from the measure based on specialty exclusion criteria. ● How Modifications Will Substantively Change Current Measure Specifications: ++ The current methodology requires that, in addition to the initial outpatient E/M service, at least one of the following services should be billed to confirm the candidate event: (1) another primary care service from any clinician group within 3 days, or (2) a second E/M primary care service OR another primary care service from the same clinician group within 90 days. The modification revised the current methodology to remove the option for the second candidate event service to be provided by a different clinician group. ++ The current methodology only requires the first service to be provided by a clinician that has not been excluded attribution based on the specialty exclusion criteria. The proposed modification revised the current methodology to require both the first and second service to be provided by a clinician that is not excluded by the specialty exclusion criteria. **Criteria for removing a clinician and their candidate events from attribution would be modified as follows:** ● Modification for Exclusion: We proposed to remove clinicians and their candidate events from attribution for the TPCC measure if a clinician is: (1) an advanced care practitioner (that is, Nurse Practitioner, Physician Assistant, Certified Clinical Nurse Specialist), and (2) part of a clinician group where all other non-advanced care practitioners are excluded based on specialty criteria. ● How Modifications Will Substantively Change Current Measure Specifications: The current methodology only excludes clinicians and their candidate events if a clinician meets service category thresholds for billing certain services (that is, global surgery, anesthesia, therapeutic radiation, or chemotherapy services) or if the specialty code on a clinician's Medicare Part B claims is one of the specialties excluded from TPCC attribution. The current methodology does not exclude advanced care practitioners from attribution based on their specialty, which is identified by the specialty code on their Medicare Part B claims. This proposed modification would exclude advanced care practitioners from attribution if all other non-advanced care practitioners in their TIN are excluded based on the specialty exclusion criteria.

Category	Description
	Except as noted herein, we proposed to retain all remaining specifications for the TPCC measure without modification. These proposed modifications are also available for review in the revised TPCC measure specifications available for download here: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*.

Category	Description
Rationale	The TPCC measure assesses the overall cost of care provided to a Medicare beneficiary, focusing on MIPS eligible clinicians, subgroups, and clinician groups who provide primary care-type services. Given its broad scope, it includes all Medicare Parts A and B costs that occur during the time period attributed to the clinician or clinician group within the performance period. The measure assesses primary care, internal medicine, and other physicians, who frequently manage patients with chronic or ongoing care needs, and non-physician clinicians (such as Physician Assistants, Nurse Practitioners, and Certified Clinician Nurse Specialists) who provide primary care and related services. We proposed to modify the TPCC measure's candidate event logic to require that both services in a candidate event are provided by the same clinician group and by a clinician with a specialty included in measure attribution. This modification would result in MIPS eligible clinicians only being attributed the costs of care for beneficiaries that have had at least two qualifying services from their clinician group, and where both services were provided by a clinician that would not be excluded from measure attribution due to the specialty exclusion. The proposed modification would more strongly demonstrate that there is an ongoing care relationship. With this proposed modification, a MIPS eligible clinician would only be attributed beneficiaries that they or their clinician group have seen at least twice, and when both candidate event services are provided by clinicians who are not excluded from TPCC based on the specialty exclusion criteria. We also proposed to modify the TPCC measure's specifications to exclude certain clinicians and clinician groups from attribution. Currently, the measure does not exclude advanced care practitioners (that is, Physician Assistants, Nurse Practitioners, and Certified Clinician Nurse Specialists) from measure attribution based on their specialty. Advanced care practitioners often provide primary care and ongoing care management services. However, some advanced care practitioners participate in MIPS through clinician groups that provide specialty care that would otherwise be excluded from the measure. In these instances, an advanced care practitioner may bill services (such as office visits) to support specialized care that are unlikely to be indicative of primary care or ongoing care management relationships. Since specialty codes on Medicare Part B claims do not include information about sub-specialization for advanced care practitioners, we would use information about their clinician group to exclude certain advanced care practitioners in specialty settings (that is, clinician groups where all physicians are excluded based on the specialty exclusion criteria). This proposed modification would limit instances in which the TPCC measure would be used to assess or evaluate costs potentially associated with highly specialized clinician groups solely due to the billing patterns of advanced care practitioners within the clinician group.

Category	Description
	Additionally, we did not propose any modifications to the TPCC case minimum of 20 beneficiaries, as set forth at § 414.1350(c)(1). This case minimum was originally established in the CY 2017 QPP final rule (81 FR 77170) and maintained in the CY 2020 PFS final rule (84 FR 62978). We based this case minimum on our interest to ensure that the majority of TINs and TIN-NPIs that were measured met a threshold of 0.4 reliability and to balance our interest in ensuring moderate reliability without limiting participation. The relationship between reliability thresholds and case minimums was further discussed in the CY 2022 PFS final rule (86 FR 65453 through 65455), establishing again that a mean reliability of 0.4 for the majority of TIN and TIN-NPIs would be used as a sufficient threshold to ensure a measure is performing as intended. We tested the reliability of the TPCC measure with the proposed modifications applied. Our testing demonstrated that mean reliability would remain high at approximately 0.9 for TINs and TIN-NPIs at the 20 beneficiary case minimum. Additionally, 100 percent of TINs and TIN-NPIs would exceed the 0.4 mean reliability threshold. Therefore, we will maintain the existing case minimum of 20 cases as set forth at § 414.1350(c)(1). Prior to proposing modifications to a cost measure through the notice-and-comment rulemaking process, we have historically subjected existing cost measures for which we are considering substantive changes to the pre-rulemaking process outlined by section 1890A of the Act. Section 1848(r)(10) of the Act provides that the pre-rulemaking requirements in 1890A of the Act are not required to apply to the selection of MIPS cost measures; however, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-interested parties workgroups and have accordingly elected for such measures to be reviewed utilizing this process, as detailed in the Measures Management System (MMS) Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview*. For TPCC, we comprehensively reevaluated the measure in use in MIPS in accordance with the process outlined in the MMS Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/comprehensive-reevaluation*. During this process, we held two public comment periods and convened a Technical Expert Panel (TEP) twice to discuss modifications. We have received robust feedback from the public about the potential modifications during this comprehensive reevaluation process and through other cost measure public comment opportunities, such as the CY 2025 PFS rule. Following the completion of the comprehensive reevaluation process, we opted not to subject the TPCC measure with these proposed modifications to the pre-rulemaking process. We considered (i) the high volume of feedback received to date on the modifications; (ii) that the scope of the modifications does not impact the intent of the measure or negatively impact measure testing results; and (iii) that there is a tradeoff in

Category	Description
	delaying updates by a year to submit the measure to the pre-rulemaking process. Based on these considerations, we proposed modifications to the TPCC measure through notice-and-comment rulemaking without having subjected the measure to the pre-rulemaking process. More information about the feedback we received from interested parties and technical expert panel(s) on the TPCC measure, and analyses that contributed to identifying the TPCC modifications, is available in the Cost measure comprehensive reevaluation (2023-2024) section of the QPP Cost Measures Information Page: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/current*.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of CMS' efforts to modify the criteria for removing a clinician and their candidate events from attribution of the TPCC measure. Several commenters stated that the exclusion of advanced care practitioners in specialist-only groups will prevent inappropriate attribution to clinicians providing specialty care and that this modification addresses concerns that they have raised about the attribution methodology.

Response: We thank the commenters for their support and for their confirmation that the modification to the candidate event exclusion criteria addresses concerns with the TPCC measure's attribution methodology. We agree that these modifications limit the possibility that the measure would be attributed to a highly specialized clinician groups due to the billing practices of advanced care practitioners.

Comment: Several commenters requested further modifications related to TPCC attribution and advanced care practitioners in multi-specialty groups. In some instances, commenters requested specific modifications, such as excluding all multi-specialty practices that are attributed based on advanced care practitioners. Another commenter requested that CMS

account for potential instances where a multi-specialty group is attributed the TPCC measure based on advanced care practitioners providing specialty care because there are other non-advanced care practitioners in the group that do not meet the specialty exclusion criteria.

Response: Multi-specialty groups often provide primary care and related services to Medicare beneficiaries and may be assessed on the TPCC measure. It is expected and appropriate that MIPS eligible clinicians across various specialties in multi-specialty groups may be assessed on the TPCC measure at the group level.

To further clarify the attribution methodology, once candidate events are identified, MIPS eligible clinicians can be attributed based on their involvement in the candidate event. The MIPS eligible clinician responsible for the candidate event is found on the initial E/M "primary care" service claim of the candidate event. Certain MIPS eligible clinicians who meet specialty or service category exclusion criteria will have their candidate events removed from attribution at the individual clinician and group level. The attribution methodology and exclusion criteria are discussed in greater detail in the TPCC Measure Information Form, available here: *https://www.cms.gov/files/zip/2026-total-capita-cost-tpcc-measure-specifications-zip.zip*.

We do believe there are instances where it is appropriate to attribute multi-specialty groups the TPCC measure based on the billing of advanced care practitioners. Advanced care practitioners, including those in multi-specialty groups, would only be attributed the TPCC measure if they provide sufficient qualifying E/M services that indicate primary care and are not otherwise excluded from the measure. If the advanced care practitioners provided sufficient excluded services (that is, 10-day or 90-day global surgery services, anesthesia services, therapeutic radiation services, or chemotherapy services) indicative of specialty care at or above a certain threshold, the advanced care practitioners and their candidate events are removed from attribution based on the service-category exclusion criteria. This is also true for any other clinicians that are not excluded based on the specialty exclusion criteria.

Comment: Several commenters requested that CMS further adjust the TPCC measure

attribution methodology to ensure that it only captures primary care providers and that it assesses costs of care within their direct control. Some commenters raised concerns about the TPCC attribution methodology for specialists, such as concerns that certain specialties would continue to be inappropriately attributed the TPCC measure, including cardiologists, surgeons, radiologists, and hospitalists. A commenter requested greater transparency in the attribution methodology in cases where specialists are attributed the TPCC measure. Another commenter raised a concern that the measure does not account for when a primary care relationship has ended between a clinician and patient. Additionally, several commenters recommended alternative methods to identify primary care relationships in an effort to increase the precision of the attribution methodology. Commenters suggested that CMS incorporate Patient Relationship Category (PRC) codes in the TPCC measure attribution methodology to further ensure accurate attribution to primary care providers. One of the commenters also recommended that CMS create more flexibilities in assigning specialty designations for advances care practitioners, such as assigning the specialty designation of the MVP in which they are participating or establishing more specific designations in the enrollment data to identify their specialty practice area.

Response: We thank the commenters for their considerations. The TPCC measure intends to capture primary care clinicians and other clinicians who provide ongoing care. Based on the current specifications, the TPCC measure excludes a list of specialties from attribution including surgical specialties, radiologists, and hospitalists, interventional cardiology, cardiac electrophysiology, and cardiac surgery. Cardiologists and advanced heart failure and transplant cardiology specialties are included, as they provide primary care and related services. However, if they provide highly-specialized care that meets the service exclusion criteria they will be excluded. To further ensure that specialists are not inappropriately attributed candidate events for TPCC, we are finalizing the modification that excluded specialists that can no longer contribute towards the second candidate event service, as outlined in Table A.1. As a result of this modification, excluded specialties will not contribute to group attribution. The detailed measure

specifications, including a list of all excluded specialties and service-category exclusions is available on the QPP Cost Measures Information Page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about*. Clinicians can review the TPCC measure specifications to anticipate whether they fall within the exclusion criteria and gather information on the likelihood of their attribution. We will also post the measure specifications on the QPP Measures & Activities Page for clinicians' reference *(https://qpp.cms.gov/mips/explore-measures?tab=costMeasures)* prior to the start of the performance period to promote transparency in the attribution methodology.

Additionally, the measure construction does incorporate indicators for the end of a primary care relationship. Primary care is ongoing and may span a long period, so TPCC measures clinicians for 1 year following an attribution event where evidence of a primary care relationship is identified. A longer attribution window allows the cost measure to capture the long-term benefits of ongoing primary care management that might not be fully realized within a short period. For example, preventive care services contribute costs to the measure when initially provided but should lower costs when measured over a sufficiently long time as they might avoid downstream costs that usually result from lack of preventive care. The clinician may continue to be attributed in a subsequent performance period if they bill new services that constitute a candidate event during an already open period of responsibility. However, if they do not bill additional services that constitute a candidate event, this will indicate the end of the primary care relationship and they will not be attributed further performance periods.

Finally, we thank the commenters for their suggestions to increase the precision of the attribution methodology. We are continuing to assess PRCs for potential future use in MIPS cost measure attribution methodology. We will also consider further updates to the attribution methodology if additional specialty designations become available for advanced care practitioners.

As a result, we believe that the TPCC measure methodology does not require additional

modifications.

Comment: A few commenters requested additional information on whether reliability and attribution improved after implementing these modifications.

Response: As stated in Table A.1 in Appendix 4, we tested the reliability of the TPCC measure with the proposed modifications applied. Our testing demonstrated that mean reliability would remain high at approximately 0.9 for TINs and TIN-NPIs at the 20-beneficiary case minimum. During comprehensive reevaluation, we also conducted preliminary testing to assess the impact of these modifications, which were considered by a TEP in March 2024. A summary of this testing and subsequent discussion is in the March 2024 PCMP TEP Summary Report, available here: *https://mmshub.cms.gov/sites/default/files/2024-pcmp-tep-summary.pdf*. We will continue to monitor measure implementation and consider additional testing that we can make available.

Comment: Many commenters supported the modifications to the candidate event logic for the TPCC measure. A commenter stated that the modification to the triggering candidate event logic will better identify ongoing care relationships.

Response: We thank the commenters for their support and we agree that the updates to the candidate event logic will more strongly demonstrate an ongoing care relationship.

Comment: A commenter opposed the updates to the candidate event logic. The commenter raised concerns for MIPS eligible clinicians in oncology because not all oncology practices bill to a single clinical group (TIN), despite operating as a single practice. Furthermore, they stated that some oncology practices may refer patients to other practices for certain treatments or services, while maintaining the patient and physician relationship, which further complicates attribution.

Response: We continue to believe that this modification is appropriate. While there may be some instances where a candidate event is no longer captured by the measure if a practice bills to multiple TINs, we did not observe a substantial drop in episodes, beneficiaries, or MIPS

eligible clinicians captured by TPCC when applying this modification in preliminary analyses, available for review in Table 3 of the March 2024 PCMP TEP Summary Report available at *https://mmshub.cms.gov/sites/default/files/2024-pcmp-tep-summary.pdf*.

Comment: Several commenters requested that CMS also apply the modifications to the candidate event logic and attribution methodology beginning in the CY 2025 performance period/2027 MIPS payment year.

Response: We thank the commenters for their request. The TPCC measure finalized for use in the CY 2025 performance period has been specified and implemented appropriately, in accordance with the CY 2020 PFS final rule (84 FR 62969 through 62975) and the measure specifications available at *https://qpp.cms.gov/docs/cost_specifications/2025-06-py2025-mif-tpcc.pdf*. Therefore, we will apply these changes to the TPCC measure beginning in CY 2026 performance period/2028 MIPS payment year and onwards.

Comment: A commenter stated that the proposed modifications to TPCC should be benchmarked after 2 years of program experience, to align with the approach used for newly introduced quality measures and ensure that there are no unintended consequences from adjustments to the specifications.

Response: We understand this comment to be referring to measures of the Medicare CQM collection type, which use flat benchmarks for their first 2 years in MIPS starting with the CY 2025 performance period/2027 MIPS payment year, in accordance with § 414.1380(b)(1)(ii)(F). MIPS cost measures are administrative claims measures, and we align with the policy used to score administrative claims quality measures instead of Medicare CQM measures. Beginning with the CY 2023 performance period/2025 MIPS payment year, CMS calculates a benchmark for an administrative claims quality measure using the performance on the measures during the current performance period, and not on a 2-year benchmark period, in accordance with § 414.1380(b)(1)(ii)(D). Similarly, cost measures are calculated based on the current performance year data in accordance with § 414.1380(b)(2)(i). The goal is to compare

clinician's cost performance to their peers' cost performance in a given performance period. CMS will continue to monitor TPCC and the potential for any unintended consequences based on the modifications to the TPCC measure specifications.

Comment: A few commenters raised concerns that TPCC may double count costs for clinicians assessed on multiple measures and requested that the measure is excluded in instances where there is another applicable measure.

Response: We do not have concerns regarding double counting costs between TPCC and other cost measures. Each measure reflects MIPS eligible clinician performance within the context of the individual measure. For example, TPCC assesses overall cost of care while episode-based measures assess costs of care for a specific procedure or condition. Having multiple cost measures available for a clinician can provide a more complete assessment of the types of care that a clinician provides. Further information about how claims data is shared within and across cost measures in a way that avoids double counting concerns is available in the "Shared Data Across Cost Measurements" document available at *https://www.cms.gov/files/document/shared-data-across-cost-measurements-3-13-20.pdf*.

Comment: Several commenters requested the removal of TPCC from MIPS, stating that TPCC holds clinicians and groups accountable for care outside of their control, assesses clinicians that do not provide primary care, and that they prefer episode-based measures.

Response: We continue to believe that it is appropriate to maintain the TPCC measure in Traditional MIPS and MVPs, as we have outlined in in the CY 2020 PFS final rule (84 FR 62969 through 62975). The TPCC measure is an important measure of cost performance in Traditional MIPS and MVPs. The measure's intent to capture broad, overall care plays a significant role in complementing the more granular information captured by episode-based measures. For example, TPCC is a key element of assessing value in the Value in Primary Care MVP. This MVP is most applicable for preventative medicine, internal medicine, family medicine, and geriatric specialties. While the measure includes Asthma/Chronic Obstructive Pulmonary

Disease (COPD), Diabetes, Depression, and Heart Failure episode-based measures to assess more specific facets of ongoing and chronic care management, TPCC is an essential piece of capturing overall primary care within the MVP.

As a broadly applicable cost measure, the TPCC measure encourages clinicians to coordinate with other clinicians while treating a patient to improve overall cost performance. This promotes shared responsibility for a patient's cost of care across providers performing ongoing care management, aligning with CMS and HHS priorities to protect federal tax dollars and help patients achieve their health goals, as outlined in the CMS Innovation Center 2025 Strategy available at *https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again*.

While the episode-based measure inventory has increased since the introduction of MIPS in 2016, there remains a large portion of Medicare spending that is not assessed by the episode-based measures. Coverage estimates of the episode-based measures and TPCC are outlined in the 2024 MIPS Summary of Cost Measures, available at *https://www.cms.gov/files/document/2024-mips-summary-costs-measures.pdf*.

Comment: Several commenters provided feedback on aspects of the TPCC measure that have not been modified, such as concerns related to the effectiveness and precision of the risk adjustment and service assignment methodology.

Response: We appreciate the commenters' feedback. We continue to believe that the TPCC measure is specified appropriately, as finalized in the CY 2020 PFS final rule (84 FR 62969 through 62975). We will consider this feedback during future maintenance and comprehensive evaluation efforts for the TPCC measure in accordance with the maintenance processes outlined by the CMS Measures Management System (MMS) (https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/overview).

Comment: A commenter recommended that CMS submit the revised TPCC measure for review and endorsement by the Consensus-Based Entity (CBE) to ensure it does not

inadvertently create disincentives for taking on patients with more complex medical needs.

Response: We thank the commenter for their recommendation. The TPCC measure was endorsed by a CBE in 2020, which is detailed in the National Quality Forum Cost and Efficiency Spring 2020 Cycle Technical Report, available at *https://digitalassets.jointcommission.org/api/public/content/926365c68be1441791340150005aacd6?v=39e48ce7*. We will discuss with the CBE to determine the appropriate next steps for the TPCC measure. Although we may pursue endorsement by the CBE, contracted in accordance with section 1890 of the Act, we are not required to use only CBE endorsed measures in MIPS as discussed in the CY 2025 PFS final rule (89 FR 98391).

After consideration of the public comments, we are finalizing the TPCC measure with modifications in Table A.1 as proposed for the CY 2026 performance period/2028 MIPS payment period and future years.

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